IMPROVING EPA'S SCIENTIFIC ADVISORY PROCESSES

HEARING

BEFORE THE

SUBCOMMITTEE ON ENVIRONMENT

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRTEENTH CONGRESS

FIRST SESSION

WEDNESDAY, MARCH 20, 2013

Serial No. 113–15

Printed for the use of the Committee on Science, Space, and Technology

Available via the World Wide Web: http://science.house.gov

U.S. GOVERNMENT PRINTING OFFICE

80–553PDF WASHINGTON : 2013

For sale by the Superintendent of Documents, U.S. Government Printing Office
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Wednesday, March 20, 2013

IMPROVING EPA'S SCIENTIFIC ADVISORY PROCESSES

WEDNESDAY, MARCH 20, 2013

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

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

LAMAR S. SMITH, Texas
CHAIRMAN

EDDIE BERNICE JOHNSON, Texas
RANKING MEMBER

Congress of the United States
House of Representatives

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Subcommittee on Environment

Improving EPA's Scientific Advisory Processes

Wednesday, March 20, 2013
10:00 a.m. -12:00 p.m.
2318 Rayburn House Office Building

Witnesses

Dr. Michael Honeycutt, Chief Toxicologist, Texas Commission on Environmental Quality

Dr. Roger McClellan, Advisor, Toxicology and Human Health Risk Analysis

Dr. Francesca Grifo, Senior Scientist and Science Policy Fellow, Union of Concerned Scientists

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

HEARING CHARTER

Improving EPA's Scientific Advisory Processes

Wednesday, March 20, 2013
10:00 a.m. - 12:00 p.m.
2318 Rayburn House Office Building

PURPOSE

The Subcommittee on Environment of the Committee on Science, Space and Technology will hold a hearing entitled *Improving EPA's Scientific Advisory Processes* on Wednesday, March 20, 2013, at 10:00 a.m. in Room 2318 of the Rayburn House Office Building. The purpose of this hearing is to examine the Environmental Protection Agency's (EPA) process for receiving independent scientific advice and to receive testimony on draft legislation to strengthen public participation, improve the process for selecting expert advisors, expand transparency requirements, and limit non-scientific policy advice among advisory bodies.

WITNESS LIST

- **Dr. Michael Honeycutt**, Chief Toxicologist, Texas Commission on Environmental Quality
- **Dr. Roger McClellan**, Advisor, Toxicology and Human Health Risk Analysis
- **Dr. Francesca Grifo**, Senior Scientist and Science Policy Fellow, Union of Concerned Scientists

BACKGROUND

EPA's Science Advisory Board (SAB) was established by Congress in the Environmental Research, Development, and Demonstration Authorization Act of 1978 (ERDDAA).[1] Under this authorization, the SAB provides scientific advice as may be requested by the EPA Administrator and interested Congressional Committees.

Since its enactment, the size and function of the SAB has evolved. ERDDAA established a minimum number of nine members, one of which is to be the designated Chair. Members are appointed by the EPA Administrator to serve a 3-year term and may be reappointed for a second 3 year term. There are currently 51 members of the chartered SAB. The SAB and its subcommittees and ad hoc subpanels provide scientific advice on a wide range of issues, including stream and wetland connectivity, hydraulic fracturing, environmental justice screening,

[1] *Public Law 95-155.*

and regulatory cost estimates.[2] The Board has also begun providing advice on the science underpinning several potential, forthcoming Agency regulatory activities.[3]

The SAB is operated in accordance with the Federal Advisory Committee Act of 1972, which requires that advisory panels have a charter and be "fairly balanced in terms of the points of view represented and the functions to be performed." According to the EPA, SAB's mission includes:

- reviewing the quality and relevance of the scientific and technical information being used or proposed as the basis for Agency regulations;
- reviewing research programs and the technical basis of applied programs;
- reviewing generic approaches to regulatory science, including guidelines governing the use of scientific and technical information in regulatory decisions, and critiquing such analytic methods as mathematical modeling;
- advising the Agency on broad scientific matters in science, technology, social and economic issues; and
- advising the Agency on emergency and other short-notice programs.[4]

Toward those goals, the chartered SAB conducts much of its work through subcommittees or subpanels focused on specific issues. Currently, these subcommittees include: Drinking Water Committee; Ecological Processes and Effects Committee; Environmental Economics Advisory Committee; Environmental Engineering Committee; Exposure and Human Health Committee; Radiation Advisory Committee; and the Chemical Assessment Advisory Committee (established January 30, 2013).[5] Under the SAB's charter,[6] these "[c]ommittees, panels, and workgroups have no authority to make decisions on behalf of the SAB and may not report directly to the Agency."

The EPA also receives advice from and manages 22 additional Federal Advisory Committees, including entities like the EPA Board of Scientific Counselors, the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel, and the Clean Air Scientific Advisory Committee (CASAC).[7] These bodies carry out a variety of advisory functions. For example, CASAC "provides independent advice to the EPA Administrator on the technical bases for EPA's national ambient air quality standards" and "addresses research related to air quality, sources of air pollution, and the strategies to attain and maintain air quality standards and to prevent significant deterioration of air quality." The Chair of CASAC also sits on the chartered SAB.[8]

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[2] http://yosemite.epa.gov/sab/sabproduct.nsf/WebProjectsbyTopicBOARD!OpenView.
[3] Dave Reynolds, "Advisors Narrow List Of Pending EPA Rules For Novel Scientific Scrutiny," Inside EPA, March 11, 2013, http://insideepa.com/201303112427282/EPA-Daily-News/Daily-News/advisors-narrow-list-of-pending-epa-rules-for-novel-scientific-scrutiny/menu-id-95.html.
[4] http://yosemite.epa.gov/sab/sabpeople.nsf/Webcommittees/BOARD.
[5] http://yosemite.epa.gov/sab/sabproduct.nsf/WebBOARD/CommitteesandMembership?OpenDocument.
[6] http://yosemite.epa.gov/sab/sabproduct.nsf/WebBOARD/currentcharter?OpenDocument.
[7] http://www.epa.gov/ocem/faca/facacomcontacts.htm.
[8] http://yosemite.epa.gov/sab/sabpeople.nsf/WebCommittees/CASAC.

EPA staff and the chartered SAB allow for some public involvement in advisory activities through the nomination of experts for committees and panels and involvement in advisory committee meetings and report developments. In response numerous comments during an SAB Session on Public Involvement in June 2011, the SAB Staff Office announced additional steps to enhance public involvement in advisory activities beginning in FY2012.[9]

LEGISLATIVE SUMMARY AND HISTORY

In the 112th Congress, then-Chairman Ralph Hall, along with current Chairman Lamar Smith and other members of the Science, Space, and Technology Committee introduced H.R. 6564, the EPA Science Advisory Board Reform Act of 2012. This legislation would have altered EPA's advisory process by: strengthening public participation and comment opportunities; changing SAB and sub-panel selection process; requiring chances for dissenting members to make their views known and the communication of uncertainties; and limiting non-scientific policy advice.

Witnesses have been asked to provide comment on discussion draft legislation similar to H.R. 6564 (language and section-by-section analysis attached).

ADDITIONAL READING

- EPA, Reorganization of the EPA Science Advisory Board (SAB): A Report of the EPA Science Advisory Board Staff Office, November 2003.
- Terry Yosie, "The EPA Science Advisory Board: A Case Study in Institutional History and Public Policy," *Environmental Science and Technology*, 1993, Vol. 27, No. 8.
- Craig S. Barrow and James W. Conrad, "Assessing the Reliability and Credibility of Industry Science and Scientists," *Environmental Health Perspectives*, 2006, 114: 153-155.
- James E. McCarthy, "Air Quality Standards and Sound Science: What Role for CASAC?" April 21, 2008, Congressional Research Service, 7-5700.
- Ronald Bailey, "Scrutinizing Industry-Funded Science: The Crusade Against Conflicts of Interest," March 2008, American Council on Science and Health.
- Joe G. Conley, "Conflict of Interest and the EPA's Science Advisory Board," Texas Law Review, November 2007.
- EPA, Peer Review Handbook, 3rd Edition.
- The National Academies, Policy on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports, May 12, 2003.
- Bipartisan Policy Center's Science for Policy Project, Improving the Use of Science in Regulatory Policy, August 5, 2009.
- The Keystone Center's Research Integrity Roundtable, Improving the Use of Science in Regulatory decision-Making: Dealing with Conflict of Interest and Bias in Scientific Advisory Panels, and Improving Systematic Scientific Reviews, September 18, 2012.
- Bruce L.R. Smith, *The Advisers: Scientists in the Policy Process* (Washington, DC: The Brookings Institution, 1992).

[9] http://yosemite.epa.gov/sab/sabproduct.nsf/WebSABSO/PublicInvolvement?OpenDocument.

- Sheila Jasanoff, *The Fifth Branch: Science Advisers as Policymakers* (Cambridge, MA: Harvard University Press, 1990).

Discussion Draft

Section-by-Section Analysis

Purpose: To amend the Environmental Research, Development, and Demonstration Authorization Act of 1978 to provide for Scientific Advisory Board member qualifications, public participation, and for other purposes.

Section 1: Short Title

This Act is entitled, "EPA Science Advisory Board Reform Act of 2013".

Section 2: Science Advisory Board

Subsection (a) MEMBERSHIP amends section 8(b) of the Environmental Research, Development, and Demonstration Authorization Act of 1978 (ERDDAA) to include the following:

(b) (1) Requires the Science Advisory Board be composed of at least nine members, with one designated as Chairman, and that these members meet at a times and places designated by the Chairman and Administrator.

(2) Requires that each member of the Board is qualified by education, training, and experience to evaluate scientific and technical information on matters referred to the Board. The Administrator is required to select Board members from nominations received, and shall ensure: (A) the scientific and technical points of view represented on the Board, as well as the function to be performed, be fairly balanced among the Board members; (B) at least ten percent of Board membership are from State, local, or tribal governments; (C) persons with substantial and relevant expertise are not excluded from the Board due to affiliation with or representation of entities that might have a potential interest in the Board's advisory activities, as long as this interest is fully disclosed to the Administrator and the public; (D) in the case of a Board advisory activity on a particular matter involving a specific party, no Board member that has an interest in that party shall participate in that activity; and (E) Board members may not participate in advisory activities that involve review or application of their own work.

(3) The Administrator is required to: (A) solicit public comments for the Board by publishing a notification in the Federal Register; (B) solicit nominations from relevant Federal Agencies; (C) make the list of nominees, as well as the entity that nominated them, public, and accept public comments on the nominees; (D) require that upon nomination, nominees file a written report disclosing financial relationships and interests, including EPA grants, contracts, cooperative agreements, and other financial assistance relevant to the Board's advisory activities for the three year period prior to nomination, as well as relevant professional activities and public statements for the five year period prior to nomination; and (E) these reports are made public for each member of the Board upon their selection, excepting specific dollar amounts.

(4) The terms of the members of the Board shall be three years and staggered to ensure that no more than one-third of total membership shall expire within a single year, and members are limited to two terms over a ten-year period.

Subsection (b) RECORD amends Section 8(c) of ERDDAA in the following ways:

In paragraph 1: (A) by inserting "risk or hazard assessment" after "at the time any proposed"; and (B) by inserting "risk or hazard assessment" after "to the Board such proposed".

In paragraph 2: (A) by inserting "risk or hazard assessment" after "the scientific and technical basis of the proposed"; and (B) by adding at the end "The Board's advice and comments, including dissenting views of Board members, and the response of the Administrator shall be included in the record with respect to any proposed risk or hazard assessment, criteria document, standard, limitation, or regulation and published in the Federal Register."

Subsection (c) MEMBER COMMITTEES AND INVESTIGATIVE PANELS amends section 8(e) of ERDDAA by adding requirements that the member committees and investigative panels: (1) be constituted and operate in accordance with other provisions of this Act; (2) do not have authority to make decisions on behalf of the Board; and (3) may not report directly to the Environmental Protection Agency.

Subsection (d) PUBLIC PARTICIPATION amends ERDDAA by adding subsection (h). Subsection (h): (1) requires the Administrator and the Board to make public all reports and relevant scientific information and provide materials to the public at the same time they are received by the Board. (2) Requires the Board to hold a public information-gathering session to discuss the state of the science relative to the advisory activity prior to conducting major advisory activities. (3) Requires the Administrator to accept, consider, and address public comments on questions to be asked of the board prior to convening a member committee or panel, and The Board, member committee, or panels shall accept, consider, and address these public comments. The Board cannot accept a question that unduly narrows the scope of an advisory activity. (4) Requires the Administrator and the Board to encourage public comments, and the public comments must be provided to the Board when received. The Board is also required to respond in writing to significant public comments. (5) Provides the public with 15 calendar days after Board meetings to provide additional comments for consideration.

Subsection (e) OPERATIONS amends ERDDAA by adding subsection (i) which requires: (1) the Board strive to avoid making policy determinations or recommendations, and explicitly distinguish between scientific determinations and policy advice. (2) The Board clearly communicates uncertainties associated with scientific advice provided to the Administrator. (3) The Board ensures that advice and comments reflect the views of the members and encourage dissenting members to make their views known to the public and Administrator. (4) The Board conducts periodic reviews to ensure its advisory activities are addressing the most important scientific issues facing the EPA.

Chairman STEWART. Good morning, everyone. The Subcommittee on Environment will come to order.

Welcome to today's hearing entitled "Improving EPA's Scientific Advisory Processes." In front of you are packets containing the written testimony, biographies, and truth-in-testimony disclosures of today's witnesses. I would now like to recognize myself for five minutes for an opening statement.

Welcome once again to this morning's hearing on the Environmental Subcommittee entitled "EPA's Scientific Advisory Processes." Former President Ronald Reagan famously said that "the government's view of the economy should be summed up in a few short phrases: if it moves, tax it. If it keeps moving, regulate it. And if it stops moving, subsidize it." The EPA's agency needs no introduction as a primary executor of the regulatory part of this formula.

Whether it is fostering air-quality regulations that could shut down large swaths of the West, undertaking thinly veiled attacks on the safety of hydraulic fracturing, or pursuing job-killing climate regulations that will have no impact on the climate, EPA's reputation as a lightning rod for controversy is well known here in Washington and throughout the country.

Less well known and understood, however, is the underlying regulatory science and scientific advisory mechanisms that the Agency uses to justify its aggressive regulatory approach. The purpose of today's hearing is to examine these processes with a particular focus on draft legislation to reform the EPA's Science Advisory Board, or SAB. Established by Congress in 1978, the SAB is intended to provide meaningful, balanced, and independent reviews of the science conducted and used by the Agency. Unfortunately, this vision often goes unrealized in actual practice. I would like to note just a few examples here.

Despite a statutory requirement that EPA's advisory panels be "fairly balanced in terms of point of view represented," the Agency routinely excludes private sector expertise while stacking these panels with individuals likely to support EPA's perspective. It is no surprise that EPA finalized a regulation on power plants in late 2011 that even the Agency admitted would cost $11 billion a year. EPA had prevented virtually all industry scientists from participating in the review of the underlying science.

Similarly, this Committee received testimony stating that, in the case of an SAB panel asked to examine EPA's hydraulic fracking research, all 22 members had "no experience in hydraulic fracturing and no understanding of current industry practices," this in an industry whose technology is rapidly changing with significant improvements incorporated into their processes nearly every day. Even worse, the Agency appears ready to double-down on this anti-business attitude I summarily dismissing on the ground private sector experts in the next fracking science review.

Meanwhile, there are unsettling Agency trends about how EPA selects its supposedly independent advisers. According to the Congressional Research Service, almost 60 percent of the members of EPA's chartered SAB and Clean Air Scientific Advisory Committee, also known as CASAC, have directly received grants from the

Agency since 2000. These advisors served as principal and co-investigators in EPA grant totaling roughly $140 million.

EPA frequently chooses panelists whose research is directly or indirectly under review. During a recent review of EPA air-quality science, 21 of the 25 panelists had their work cited by the EPA and the Chair of the panel was footnoted more than 80 times.

Many of the panelists have clearly taken sides are made public pronouncements on issues they advise about. For example, a lead reviewer of EPA's hydraulic fracking study published in anti-fracking article entitled "Regulate, Baby, Regulate."

This hardly sounds like a recipe for a critical or balanced examination. Yet EPA routinely touts the work of its independent science advisors in promoting and defending its controversial regulatory agenda. The record is clear: the SAB is ripe for improvement.

Accordingly, we will discuss draft legislation that would address these concerns—the EPA Science Advisory Board Perform Act of 2013. This language is similar to the bill introduced in the 112 Congress by then-Chairman Ralph Hall. The draft bill would reform the SAB and its subpanels by expanding transparency requirements, improving the process for selecting expert advisers, strengthening public participation, and limiting non-scientific policy advice.

The concepts contained in this proposed legislation did not arise out of thin air; rather, they are principles that came from the EPA's own Peer Review Handbook, the National Academies' Conflict-of-Interest Policy, existing Federal ethics requirements on Special Government Employees, and recommendations from past Science Committee testimony and other outside groups.

Let me conclude by making this important point: if the EPA scientific process is viewed as being biased less or than willing to consider every point of view, their credibility suffers. This serves neither the EPA, American businesses, nor American citizens. Independent, balanced, and transparent review of EPA science offers a critical check on the Agency that frequently views the world through its regulatory lens. Commonsense reforms that improve scientific advice should make EPA's regulatory end-products more credible, and I look forward to our witnesses' unique perspective on these issues.

I now recognize the Ranking Member, the gentlewoman from Oregon, Ms. Bonamici, for an opening statement.

[The prepared statement of Mr. Stewart follows:]

PREPARED STATEMENT OF SUBCOMMITTEE CHAIRMAN CHRIS STEWART

Welcome to this morning's hearing of the Environment Subcommittee entitled Improving EPA's Scientific Advisory Processes.

Former President Ronald Reagan famously said that "government's view of the economy could be summed up in a few short phrases: If it moves, tax it. If it keeps moving, regulate it. And if it stops moving, subsidize it." The Environmental Protection Agency needs no introduction as the primary executor of the regulatory part of this formula.

Whether it is promulgating air quality regulations that could shut down large swaths of the West, undertaking thinly veiled attacks on the safety of hydraulic fracturing, or pursuing job-killing climate regulations that will have no impact on the climate, EPA's reputation as a lightning rod for controversy is well known here in Washington and throughout the country.

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- Despite a statutory requirement that EPA's advisory panels be "fairly balanced in terms of point of view represented" the Agency routinely excludes private sector expertise while stacking these panels with individuals likely to support EPA's perspective. It is no surprise that EPA finalized a regulation on power plants in late 2011 that even the Agency admitted would cost $11 billion a year; EPA had prevented virtually all industry scientists from participating in the review of the underlying science.
- Similarly, this Committee received testimony stating that, in the case of an SAB panel asked to examine EPA's hydraulic fracturing research, all 22 members had "no experience in hydraulic fracturing and no understanding of current industry practices." This, in an industry whose technology is rapidly changing, with significant improvements incorporated into their process nearly every day. Even worse, the Agency appears ready to double-down on this anti-business attitude by summarily dismissing on-the-ground private sector experts in its next fracking science review.

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- According to the Congressional Research Service, almost 60 percent of the members of EPA's chartered SAB and the Clean Air Scientific Advisory Committee (also known as "CASAC") have directly received grants from the Agency since 2000. These advisors served as principal or co-investigators for EPA grants totaling roughly $140 million dollars.
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Independent, balanced, and transparent review of EPA science offers a critical check for an Agency that frequently views the world through its regulatory lenses. Common sense reforms that improve scientific advice should make EPA's regulatory end-products more credible, and I look forward to our witnesses unique perspectives on these issues.

Ms. BONAMICI. Thank you very much, Mr. Chairman.

Today, the Subcommittee meets for a hearing on the quality of the science being used by the Environmental Protection Agency. When I first read the title of the hearing, "Improving EPA's Scientific Advisory Process," I felt encouraged that this would be an opportunity to explore areas of bipartisan agreement on how to improve an important Federal agency. I am sure that my colleagues agree that if and when there are problems in a government entity for which the mission is to protect public health and the environment, we should be steadfast in identifying any problem and work together to find meaningful solutions.

According to the hearing charter, the purpose of this hearing is to receive independent scientific advice and testimony on draft legislation that seeks to strengthen public participation, improve the process for selecting expert advisers, expand transparency requirements, and limit nonscientific policy advice within the EPA's scientific advisory process. All of these are good government principles that I support.

Like many of my colleagues on the panel, I have heard from constituents who are frustrated with EPA decisions, EPA processes, or both. Many of those constituents tell me that what they need from the EPA is consistency and efficiency. On closer examination of the discussion draft of the bill, however, I noted that the provisions will not improve the Science Advisory Board structure or operation but instead would likely limit the quality of scientific advice the EPA receives. These provisions appear to tie the EPA's hands by denying the Agency access to a vast pool of our country's most expert scientists and researchers in environmental science and health.

Last Congress, there was a very similar bill introduced, only the prior version contained a provision that would have resulted in many, if not most, scientists from academic institutions being eliminated from the EPA's Science Advisory Boards and being replaced by industry-funded experts. I am glad to see that my colleagues in the majority have eliminated that provision in this current draft.

Although that provision is no longer there, other parts of the draft bill appear to do the same thing. By eroding requirements that are in place under the Ethics in Government Act and by creating an unnecessary legal conundrum because of inconsistencies with the Federal Advisory Committee Act, FACA, under which thousands of Boards, including EPA's Science Advisory Boards, operate and have operated since inception.

To be clear on one point—and I trust that this is an area where my Republican colleagues and I agree—I am not opposed to industry-funded experts participating on Scientific Advisory Boards or in the peer-review process at the EPA. Their expert insight into processes and industry conduct can provide valuable guidance to an advisory body. That said, the Science, Space, and Technology Committee in the House of Representatives should not be putting forth legislation that undermines ethics requirements and other requirements that have governed thousands of advisory boards through the Executive Branch since 1972 with the end result being an overrepresentation of industry voices on the Science Advisory Boards.

EPA's science is tied to a mission, a mission to protect public health through environmental regulation. Scientific research, knowledge, and technical expertise are fundamental to EPA's mission and inform its regulatory functions. That need for expertise is exactly why Congress created advisory boards such as the Science Advisory Board, to provide independent advice on the science, which in turn allows the EPA Administrator to make sound regulatory decisions.

I hope that instead of undermining the scientific advice EPA receives, we build upon EPA's scientific legacy. I hope we don't spend our time condemning American scientists and researchers simply because they are affiliated with research universities. And I want to note that under existing law scientists already recuse themselves from activities that directly or indirectly relate to finding decisions that are—that affect them, besides suggesting that American scientists and researchers are adversaries of good science is not good for our country.

Before yielding back, Mr. Chairman, I would like to enter into the record several letters sent to the Committee by various groups and individuals expressing their concerns about provisions in the bill. These letters are from concerned citizens, science, and environmental organizations, and individuals within the scientific research community around the country. I look forward to the testimony today and the questions. And with that, Mr. Chairman, I yield back.

[The prepared statement of Ms. Bonamici follows:]

PREPARED STATEMENT OF SUBCOMMITTEE RANKING MEMBER SUZANNE BONAMICI

Thank you, Chairman Stewart. Today the Subcommittee meets again for a hearing on the quality of the science being used by the Environmental Protection Agency. When I first read the title of this hearing, "Improving EPA's Scientific Advisory Process," I felt encouraged that this would be an opportunity to explore areas of bipartisan agreement on how to improve an important federal agency. I am sure my colleagues agree that, if and where there are problems in a government entity for which the mission is to protect public health and the environment, we should be steadfast in identifying any problem and work together to find meaningful solutions.

According to the hearing charter, the purpose of this hearing is to receive independent scientific advice and testimony on draft legislation that seeks to strengthen public participation; improve the process for selecting expert advisors; expand transparency requirements; and limit non-scientific policy advice within the EPA scientific advisory process. All of these are good government principles that I support. Like many of my colleagues on this panel, I have heard from constituents who are frustrated with EPA decisions, EPA processes, or both. Many of those constituents tell me that what they need from EPA is consistency and efficiency.

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To be clear on one point—and I trust that this is an area where my Republican colleagues and I agree: I am not opposed to industry-funded experts participating on the Science Advisory Board or in the peer review process at the EPA. Their expert insight into processes and industry conduct can provide valuable guidance to an advisory body. That said, the Science, Space, and Technology Committee in the House of Representatives should not be putting forth legislation that undermines ethics requirements and other requirements that have governed thousands of advisory boards throughout the executive branch since 1972, with the end result being an overrepresentation of industry voices on Science Advisory Boards.

EPA's science is tied to a mission to protect public health through environmental regulation. Scientific research, knowledge, and technical expertise are fundamental to EPA's mission and inform its regulatory functions. That need for expertise is why Congress created advisory bodies such as the Science Advisory Board (SAB) to provide independent advice on the science, which in turn allows the EPA Administrator to make sound regulatory decisions.

I hope that, instead of undermining the scientific advice EPA receives, we build upon EPA's scientific legacy. I hope that we don't spend our time today condemning American scientists and researchers simply because they are affiliated with a research university. And I want to note that scientists already recuse themselves from activities that directly or indirectly relate to finding decisions that affect them. Besides, suggesting that American scientists and researchers are adversaries of good science is not good for our country.

Before yielding back, I would like to enter into the record letters sent to the Committee by various groups and individuals expressing their concerns about the provisions in the bill. These letters are from concerned citizens, science and environmental organizations, and individuals within the scientific research community around the country.

Chairman STEWART. Thank you, Ms. Bonamici.

Regarding your request for submitting your letters, without objection, so ordered.

[The information appears in Appendix II]

Chairman STEWART. I would note that not all of these letters from environmentalists mention concerns in H.R. 6564 that may not be relevant to the discussion draft considered today, which I think you pointed out in your opening statement.

If there are Members who wish to submit additional opening statements, your statements will be added to the record at this point.

At this time I would like to introduce our witnesses. And before I do, thank you for taking the opportunity and being with us today. Thank you for your service to your country and for your expertise in this matter.

Our first witness is Dr. Michael Honeycutt, the Chief Toxicologist for the Texas Commission on Environmental Quality. He has been employed by Texas Commission on Environmental Quality since 1996 and has managed the division of 14 toxicologists since 2003. His responsibilities include overseeing health affects, reviews of the air permit applications, overseeing the review of the results of Ambient Air Monitoring Projects, and overseeing the reviews of Human Health Risk Assessments for hazardous waste sites.

Our second witness is Dr. Roger McClellan, an Advisor of Toxicology and Human Health Risk Analysis. Dr. McClellan has served as an Advisor to numerous public and private organizations. He has served on the Senior Advisory Committees for eight Federal agencies, he is the past Chairman of the Clean Air Scientific Advisory Committee, the Environmental Health Committee, Research Strategies Advisory Committee, and a member of the Executive Committee Science Advisory Board, U.S. Environmental Protection

Agency. He received his doctorate from Washington State University in 1960.

Our final witness today is Dr. Francesca Grifo, a Senior Scientist and Senior Policy Fellow at the Union of Concerned Scientists. Dr. Grifo came to UCS in 2005 from Columbia University where she directed the Center for Environmental Research and Conservation Graduate Policy Workshop and ran the Science Teachers Environmental Education Program. Prior to that, she was Director of the Center for Biodiversity and Conservation and a Curator at the Hall of Biodiversity at the American Museum of Natural History in New York. Dr. Grifo earned her doctorate in botany from Cornell University.

It is clear that all of these witnesses have great expertise and background that could lend to this subject. As our witnesses should know, spoken testimony is limited to five minutes, after which the Members of the Committee will have five minutes to each ask questions.

I now recognize Dr. Honeycutt for five minutes for his testimony.

TESTIMONY OF DR. MICHAEL HONEYCUTT,
CHIEF TOXICOLOGIST,
TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

Dr. HONEYCUTT. Good morning, Mr. Chairman and Members of the Committee. My name is Dr. Michael Honeycutt. I am Director of the Toxicology Division at the Texas Commission on Environmental Quality. I thank you for this opportunity to testify.

A few years ago, I attended a scientific meeting in North Carolina where I struck up a conversation with a scientist who had been a member of the lead Clean Air Science Advisory Committee, or CASAC. I gave him my view on EPA's lowering of the lead standard in 2008 and he told me that he wished he had known this information when they were deliberating the lead standard and asked why I hadn't made comments. I told him that I had submitted written comments and he replied we don't read the written comments. You have to go to the public meetings to make your case in person.

Why bother going through the pretense of having written comments to the CASAC if you are not going to read them? Oral testimony at the CASAC meetings is limited to three or five minutes, hardly enough time to present a thorough argument. This illustrates the need for EPA's advisory panels to be balanced. Having balanced panels brings all the information into consideration which reduces "group think" and leads to better policy decisions.

In the past, the CASAC has been relatively well-balanced in terms of expertise and range of opinions. However, in recent years the trend has been towards inclusion of more epidemiologists from academia at the exclusion of other areas of expertise such as toxicologists and risk assessors with little or no representation of well-qualified scientists from states and industry. This is perhaps the results of a misunderstanding of the role of scientists play in these organizations together with a misplaced perception of potential conflicts of interest.

I went to school with and have worked with many scientists who now work for industry. I know their companies did not ask them

to check their ethics and morals at the door when they took their jobs in industry. Given that academicians bring their own biases into the CASAC, there is no reason to believe that well-qualified experts from state agencies, consulting firms, or industry would be disproportionately biased.

One concern that is often raised when deciding to exclude certain parties in the process of EPA peer review is bias due to sources of funding. I believe that receiving funding from the EPA in the form of research grants can also be seen as a potential source of bias. Under the current system, the EPA can select who it wishes to fund, choose key studies to support regulatory decisions, place the authors of those studies on the CASAC, and then ask their opinion on the resulting analysis and policy. Clearly, this poses a potential conflict of interest, even if the study authors recuse themselves from discussions which directly addresses their own work.

We would instead propose a more balanced approach such as that employed by the nonprofit organization Toxicological Excellence in Risk Assessment, or TERA. TERA believes, and we concur, that an objective evaluation by independent experts with a variety of viewpoints is critical to the credibility of any peer review. TERA strives to include a range of perspectives on each panel, including diverse professional affiliations. The evaluation of real or perceived bias or conflict of interest is an important consideration for both peer review and consultation panels and every effort is made to avoid conflicts of interest and biases that would prevent a panel member from giving an independent opinion on the subject.

TERA's Conflict of Interest Policy identifies the following situations as examples of those that would create a real or perceived conflicts of interest: working for an organization that sponsors or contributes to the document to be reviewed, having direct personal financial investments benefiting from the outcome of the review, or authoring or providing significant comments on the document being reviewed.

The TERA Conflict of Interest Policy also discusses bias. For these reviews, the term bias means a predisposition towards the subject matter under consideration that could influence the candidates of viewpoint. Examples of bias would be situations in which a candidate: as previously taken a public position on the subjects to be discussed or is affiliated with an industry, governmental, public interest, or other group with a partiality regarding the subjects to be discussed.

As you can see from these examples, such potential conflicts or biases could apply equally to academicians as they may to scientists from industry or any other organization. Therefore, it is our belief that there is a need for reconsideration of current conflict-of-interest policies regarding EPA advisory panels. There is also much improvement needed with regards to a balanced peer review that incorporates numerous perspectives and areas of expertise. We believe that these changes will result in a stronger peer review process in ultimately better policy decisions.

The measures outlined in the bill are common sense and already in use by other groups such as the National Academy of Sciences and TERA. You will hear others testify that EPA has ample guid-

ance on conflict of interest, bias, and balance. The problem is they don't consistently follow it.

Thank you again for the opportunity to speak with you today and I would be happy to answer any questions you might have.

[The prepared statement of Dr. Honeycutt follows:]

Testimony to the Committee on Science, Space, and Technology
Subcommittee on Environment
March 20, 2013

"Improving EPA's Scientific Advisory Processes"

Michael E. Honeycutt, Ph.D.
Director, Toxicology Division
Texas Commission on Environmental Quality
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(512) 239-1793

Good morning, Mr. Chairman and members of the committee. My name is Dr. Michael Honeycutt. I am director of the Toxicology Division at the Texas Commission on Environmental Quality. Thank you for this opportunity to testify.

A few years ago, I attended a scientific meeting in North Carolina where I struck up a conversation with a scientist who had been a member of the lead Clean Air Science Advisory Committee, or CASAC. I gave him my view on EPA's lowering of the lead standard in 2008 and he told me he wished he had known this information when they were deliberating the lead standard and asked why I hadn't made comments. I told him we had submitted written comments. He replied, "We don't read the written comments. You have to go to the public meetings to make your case in person." Why bother going through the pretense of having written comments if the CASAC is not going to read them? Oral testimony at the CASAC meetings is limited to 3 or 5 minutes, hardly enough time to present a thorough argument. This illustrates the need for EPA's advisory panels to be balanced. Having balanced panels brings all information into consideration which reduces "group think" and leads to better policy decisions.

In the past, the CASAC has been relatively well-balanced in terms of expertise and range of opinions. However, in recent years the trend has been towards inclusion of more epidemiologists from academia, at the exclusion of other areas of expertise, such as toxicologists, and with little or no representation of well-qualified scientists from states and industry. This is perhaps the result of a misunderstanding of the role scientists play in these organizations together with a misplaced perception of potential conflicts of interest. I went to school with and have worked with many scientists who now work for industry. I know their companies did not ask them to check their ethics and morals at the door when they took their jobs in industry. Given that academicians bring their own biases into the CASAC, there is no reason to believe that well-qualified experts from state agencies, consulting firms, or industry would be disproportionately biased.

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in the form of research grants could also be seen as a potential source of bias. Under the current system, the EPA can select who it wishes to fund, choose key studies to support regulatory decisions, place the authors of those studies on the CASAC, and then ask their opinion on the resulting analysis and policy. Clearly, this poses a potential conflict of interest, even if the study authors recuse themselves from discussions which directly address their own work.

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The measures outlined in the bill are common-sense and are already in use by other groups such as the National Academy of Sciences and TERA. You will hear others testify that EPA has ample guidance on conflict of interest, bias, and balance. The problem is they don't consistently follow it.

Thank you again for the opportunity to speak with you today and I would be happy to answer any questions you may have.

Michael E. Honeycutt, Ph.D.
Director, Toxicology Division
Texas Commission on Environmental Quality

Dr. Honeycutt is the director of the Toxicology Division of the Texas Commission on Environmental Quality (TCEQ). He has been employed by the TCEQ since 1996 and has managed the division of 14 toxicologists since 2003. His responsibilities include overseeing health effects reviews of air permit applications, overseeing the review of the results of ambient air monitoring projects, and overseeing the reviews of human health risk assessments for hazardous waste sites. Dr. Honeycutt spearheaded the updating of TCEQ's Effects Screening Levels (ESLs), or toxicity factors for chemicals. The current TCEQ ESL derivation procedure has been through two independent external scientific peer reviews and multiple rounds of public comment (http://www.tceq.texas.gov/toxicology/esl/guidelines/about.html). Dr. Honeycutt serves as a technical resource for TCEQ management and staff on issues concerning air and water quality, drinking water contamination, and soil contamination. He also serves as an expert witness in public and state legislative hearings, participates in public meetings, and has conducted hundreds of media interviews.

Dr. Honeycutt is an adjunct professor at Texas A&M University, has published numerous articles in the peer-reviewed literature, serves or has served on numerous external scientific committees, and has provided invited testimony at Congressional hearings.

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Chairman STEWART. Thank you, Dr. Honeycutt.
Dr. McClellan?

TESTIMONY OF DR. ROGER MCCLELLAN, ADVISOR, TOXICOLOGY AND HUMAN HEALTH RISK ANALYSIS

Dr. MCCLELLAN. Good morning, Mr. Chairman, Members of the Subcommittee. Thank you for the invitation to share my views with you on approaches to "Improving EPA's Scientific Advisory Processes." I requested my written comments be entered into the record in their entirety.

I applaud the Subcommittee for holding a hearing on this important topic. The receipt of sound scientific advice from scientists and engineers outside of EPA is of paramount importance to the Agency fulfilling its mandated responsibilities for protection of human health and the environment. The comments I offer today draw on 50 years of experience offering advice to public and private organizations, as well as my receipt of advice as a scientist and research manager.

My service as a Scientific Advisor to the EPA began with the creation of the Agency. The new EPA included an Environmental Radiation Program previously located in U.S. Public Health Service. The transfer of the program to EPA included transfer of the environmental radiation exposure advisory committee that I would soon chair. Last summer, I provided advice to the Agency on its Multi-Pollutant Air Quality Program.

During the intervening 40 years, I have served as a member of SABs, Executive Committee, and on numerous specific committees, including service as Chair of the Clean Air Scientific Advisory Committee, it is clear from the amount of time that I have spent in those activities now measured in years that I think they are of great value to the Agency. Moreover, I think the advisory committee activities can be improved to substantially enhance their value to the EPA, to the Nation, and to the participants. The changes in legislation proposed by the Subcommittee are a small step in the right direction. However, more is needed.

I suggest that we start with a comprehensive coordinated internal and external review of all of EPA's advisory committees across all of its offices and programs and their linkage to relevant authorizing legislation and the Federal Advisory Committee Act.

Second, the review should focus on the purpose of each advisory activity and the efficiency and effectiveness of the past activities and how they can be further enhanced.

Three, the review should consider how the advisory process can be broadened to beyond the current focus on using advisors and consultants selected from a small portion of the scientific community to include individuals drawn from a national pool of talent, including those employed in the private sector.

Four, the review should consider how best to structure future advisory activities so they focus on obtaining scientific advice unfettered by any ideological linkage to how the advice may advance the Agency's current policy or political goals.

Five, the review should also focus on how to enhance public participation and transparency in the nomination and selection of advisors and consultants, because this is a very blurred boundary, in-

cluding EPA's internal processes for selecting those individuals. This review should include what I call the aspects of the selection process carried out behind the doors of the Administrator's office.

Six, the reviews should consider the role of Science Advisory Committees in addressing charge questions addressed and developed by the Agency staff, which typically have preordained answers versus obtaining advice generated by committee members based on their broad view of scientific issues and science.

Seven, special attention should be given to recent actions to select members of the Hydraulic Fracking Impact and Polychlorinated Biphenyl Review Committees. Nominees for both committees represent a much-needed broader cross-section of scientific talent then customarily considered for appointment to EPA committees. I urge the Agency to select the best qualified individuals from that broad talent pool, including knowledgeable scientists and engineers employed in the private sector.

In summary, critical review of EPA's scientific advisory process will identify ways to enhance the advisory process that will improve EPA's ability to protect human health and the environment now and in the future.

I will be pleased to address any questions you may have. Thank you again for the opportunity to appear at this hearing addressing an extremely important topic. Thank you.

[The prepared statement of Dr. McClellan follows:]

STATEMENT OF

Roger O. McClellan
Advisor, Toxicology and Human Health Risk Analysis
Albuquerque, New Mexico

Before the

Subcommittee on Environment of the Committee on Science, Space and Technology
U.S. House of Representatives

Hearing on "Improving EPA's Scientific Advisory Processes"

March 20, 2013

Major Points of Testimony of Roger O. McClellan – March 20, 2013

(1) The U.S. Environmental Protection Agency's approach to creating and using scientific advisory committees and panels has continued to evolve over the 40 plus year history of the Agency. The rate of change needs to accelerate.

(2) The Scientific Advisory Committee activities are only loosely guided by specific statutes and heavily influenced by the Federal Advisory Committee Act.

(3) The proposed legislation advanced by the Sub-Committee has some clear strengths which should aid in further improving the scientific advisory committee process. I am concerned that it is narrow in its focus.

(4) The potential for major improvements in the EPA's advisory committee process requires (a) a broad review of past EPA advisory committee activities operations, (b) identification of best practices based on EPA experience and experience in both the public and private sector, and (c) potential modifications of the Federal Advisory Committee Act. The in-depth review needs to consider the interface with the public, advisory committee responsibilities and internal EPA deliberations (behind the Administrator's door) involving appointment of both committee members and consultants.

(5) Changes in the process should seek to engage the broader scientific community including scientists and engineers employed in the private sectors that are currently under-utilized in EPA's Advisory Committee activities either as Committee Members or Consultants.

(6) Changes in the advisory committee process should be directed toward achieving greater transparency in all phases of the nomination and appointment process, reduce bias related to past or future funding, avoid bias related to a Committee Member or Consultant's alignment with the Agency's policy goals and enhance true public participation from all sectors of the U.S. economy.

Good Morning, Mr. Chairman and Members of the Subcommittee. Thank you for the invitation to present my views on approaches to "Improving EPA's Scientific Advisory Processes."

My biography is attached to this statement (Attachment 1). Since 1999, I have served as an Advisor to public and private organizations on issues related to air quality in the ambient environment and workplace drawing on more than 50 years of experience in comparative medicine, toxicology, aerosol science, and risk analysis. Prior to 1999, I provided scientific leadership for two organizations – the Chemical Industry Institute of Toxicology (1988-1999) in Research Triangle Park, NC and the Lovelace Inhalation Toxicology Research Institute (1966-1988) in Albuquerque, NM. The Chemical Industry Institute of Toxicology (now The Hamner Institutes for Health Sciences, was a not-for-profit research organization funded primarily by the chemical industry. The Lovelace Inhalation Toxicology Research Institute, continuing today as part of the Lovelace Respiratory Research Institute, was a non-profit research institute funded with both public and private funds. Both organizations, under my leadership, earned an international reputation for developing scientific information under-girding occupational and environmental health standards. During my career, I have held adjunct faculty appointments at 8 different universities and held major leadership roles in scientific organizations with membership from all sectors of the economy. The USA is fortunate to have well-qualified scientists engaged in all sectors.

The testimony I offer today also draws on my experience serving on numerous scientific advisory committees. This has included service on many EPA Scientific Advisory Committees from the origin of the Agency starting soon after the U.S. Environmental Protection Agency (EPA) was created by President Richard M. Nixon by Executive Order. At the time I was serving as Chair of the Environmental Radiation Exposure Committee to the U.S. Public Health Service (USPHS). When the USPHS radiation protection activities were transferred to the new EPA, the Environmental Radiation Exposure Advisory Committee became the responsibility of EPA along with dozens of other Advisory Committees that had operated as part of EPA's predecessor Agencies such as the National Air Pollution Control Administration. The Bureau of the Budget, the predecessor to the current Office of Management and Budget noted the large number of Advisory Committees and the hundreds of consultants. The Bureau of Budget thought there must be a more efficient way for the new Agency to secure scientific advice. The EPA responded, after seeking informal consent from the Congress, by creating a Science Advisory Board (SAB) under the Chairmanship of the late Dr. Emil Mrak, then Chancellor of the University of California-Davis. The SAB had umbrella committees organized along disciplinary lines; the key committees were Health, Engineering, and Ecology. I argued for an issue orientation of the committees and lost with my colleagues noting that "birds of a feather were comfortable together, that is the way we are organized in Academic institutions. Perhaps the radiation science field is different, so we will keep your Committee and have you join the SAB Executive Committee."

In one of my files I have a photograph of Administrator William Ruckelhaus providing me a certificate making my appointment official. Most of the early advisory attention focused on each Committee advocating for a bigger share of the budget from the EPA's newly created centralized Office of Research and Development.

One of the first major issues the EPA had to address was airborne Pb. The Natural Resources Defense Council (NRDC) had sued the EPA to have Pb listed as a criteria air pollutant under the Clean Air Act Amendments of 1970. When EPA lost the suit at the Appeals Court, it had to proceed with developing a Criteria Document to support its issuance of a National Ambient Air Quality Standard for Pb. Administrator Douglas Castle, on the advice of Dr. Mrak as Chair of the SAB, asked me to chair an *ad hoc* Committee to review the draft criteria document on airborne Pb. The Administrator appointed an appropriately diverse committee with multiple scientific and engineering disciplines represented. Within a week of the appointments being announced, I received a telephone call from one of the Committee members telling me that he had two problems with the Committee. One problem, as he expressed it, was that two committee members were "lackeys/toadies of industry." The second problem of concern to him was my serving as Chair – "I do not think you will advocate for a stringent airborne Pb NAAQS." Needless to say, the deliberations of the Committee, and especially the hallway conversations, were contentious. As the deliberations proceeded the EPA wisely decided to remove the recommendation of a specific Pb NAAQS from the criteria document recognizing that the concentration and averaging time were policy decisions. I am proud to note that when the ad hoc airborne Pb standard committee concluded its work the lead attorney from the NRDC congratulated me on my leadership of the Committee.

Thirty five years later two central concerns with EPA's Advisory Committee activities relate to (a) the role of scientists employed or engaged by industry versus academic scientists, and (b) the distinction between scientific advice and policy decisions.

Over the subsequent years I have served on the order of two dozen EPA Advisory Committees, including Chairmanship of a number of Committees and more than 20 years of service on the SAB Executive Committee. The SAB Executive Committee, consisting of about 12 individuals who chaired major SAB committees or had at-large appointments served a valuable role in coordinating the activities of multiple committees and, most importantly, advising the EPA Administrator on major scientific issues. I am disappointed the EPA SAB no longer has this kind of Executive Committee.

I am proud to say that the activities of the *ad hoc* Committee reviewing the Pb Criteria Document had a small role in the Congress amending the Clean Air Act in 1978 to formally require the EPA Administrator to appoint a Clean Air Scientific Advisory Committee (CASAC). I am pleased to have served as Chair of CASAC and in one of the seven positions mandated by the Clean Air Act and as a consultant on numerous CASAC Panels that considered all of the criteria pollutants. I note the role of both members of CASAC and consultants. In my opinion, appointment of CASAC members and consultants serves equal attention. The consultants frequently out-number the CASAC members. My last CASAC service was on the Particulate Matter (PM) Panel (2000-2007). The CASAC and the PM Panel struggled over the distinction between offering scientific advice and attempting to mandate the specific level of the NAAQS for $PM_{2.5}$. I was a minority on the Panel arguing that the specific concentration level and statistical forms of the NAAQS were inter-related policy decisions that should be informed by science. Science alone cannot identify the concentration and statistical form requisite to setting a NAAQS consistent with the language of the Clean Air Act. I have addressed this issue in a recent paper I authored entitled "Role of Science and Judgment in Setting National Ambient Air

Quality Standards: How low is low enough?" *Air Quality and Atmospheric Health* 5: 243-258, 2012.

In addition to serving on numerous EPA Advisory Committees, I have served on Advisory Committees to essentially all of the federal agencies that are concerned with environmental and occupational factors influencing the health of individuals and populations. I have also served on various committees of the National Research Council and the Institute of Medicine of which I am a member. In many cases, the issues at hand were at the interface between the physical and engineering sciences and the biological and medical sciences. Each of these disciplinary areas has different traditions and approaches to defining what is known and unknown on a given subject.

An issue of major concern for scientific advisory committees, irrespective of the issue being addressed, is how the deliberations and actions of the committee are influenced by funding the Committee members have received in the past or may receive in the future. This issue is of heightened interest as both federal and private sectors support for science are increasingly constrained. Indeed, the top priority for many organizations that are science-based is what can be done to make certain their scientific constituency receives its "fair share" of funding.

Many scientists hold the view that funding from federal agencies comes with no strings attached while anyone receiving private sector funding is indentured. In short, academic scientists are free of bias and conflicts of interest. I think such a viewpoint is open to question when the funding agency, such as the EPA, is also a regulatory agency. In my opinion, the agency needs to focus on reducing scientific uncertainty on a range of issues and take special precautions to avoid creating a funding environment focused on creating more stringent regulations. The creation of a more stringent standard or regulation should not be viewed as a criterion of success.

This brings us back to the importance of distinguishing between evaluation of the science and scientific advisory committees avoiding the temptation of entering the policy arenas and offering policy judgments. This is dangerous turf because many policy makers would like to say the science dictated the difficult policy decision; the Administrator was a mere bystander.

I am of the opinion that private sector funding is of critical importance to advancing scientific knowledge and its application. However, the interface between industry-funded science and its use in informing policy decisions needs the same kind of scrutiny as the science created with public funding.

An important underlying concern for the use of science to inform policy decisions is the availability of the underlying data for review and, indeed, re-analysis by others. In my opinion, any science used in the federal regulatory process should have been published in a high-quality peer-reviewed journal and the underlying data must be made available to qualified scientists for review and potential re-analysis. Key data used in the setting of several of the NAAQS in the past have not met the second test. As one academic scientist noted, "I do not want some industrial-hired gun wading through my data." I applaud the Johns Hopkins University team that created the National Morbidity and Mortality Air Pollution data set, used extensively in the

setting of several NAAQS, for making publicly available to others. My colleague, Dr. Suresh Moolgavkar, and I have recently used the NMMAPS data set to explore alternative approaches to data analysis (Moolgavkar, SH, McClellan, RO, et al, Time-Series Analyses of Air Pollution and Mortality in the United States: A Subsampling Approach. *Environ. Health Perspectives* 121(1): 73-78, 2013.). Likewise, I applaud the National Institute of Occupational Safety and Health (NIOSH) and the National Cancer Institute (NCI) for seeking ways to make the Diesel Exhaust in Miners Study (DEMS) available to qualified investigators. The complete data set acquired by federal employees and collaborators at a cost of over $12 million needs to be reviewed and re-evaluated by other scientists before it is used to establish federal regulations and standards.

Before leaving my discussion of service on EPA Advisory Committees, I would like to briefly note an EPA Committee I did not serve on – the CASAC Ozone Panel whose deliberations started in the early 2000s and concluded in 2008. When the CASAC Ozone Panel was being formed, I was encouraged by the Chair of CASAC to self-nominate for service on the Panel. I did so. Some months later I received a call from a Reporter asking if I had seen the letter a prominent NGO had sent to SAB concerning my services on the Panel. I said no. He said you need to see the comments; they are not very flattering. I promptly called the SAB offices and inquired about the letter. The SAB staffer acknowledged receipt of not one, but two letters concerning my potential service and that of two well-qualified colleagues. I asked if he would share the letters with me. His response was "I think you will need to file a Freedom of Information Act (FOIA) request." I told him "That is ridiculous – my fax machine is available and if I did not receive the letters within an hour I will take the matter up with the Administrator and my elected Senators and Representatives." I promptly received the letters via fax. The letters from two different NGOs were virtually identical. They questioned how I could be considered for membership on a CASAC Panel when I had previously served as President and CEO of the Chemical Industry Institute of Toxicology, a research laboratory principally funded by the chemical industry. To top it off, they suggested I was not qualified professionally to serve on the Panel since I was trained as a Veterinarian.

While I can appreciate the agency may wish to solicit comments on nominees to particular Committees, I think it should be with the understanding that any comments received by the Agency will be shared with the nominee. Indeed, if an organization is moved to comment on a nominee the organization should be willing to directly confront the nominee by sharing their concerns with the nominee. Appointments to scientific advisory committees should be made in an open and transparent manner and not influenced by sub rosea innuendos as to their qualifications. I will never know if those two letters influenced the Agency's decision to not appoint me to the Ozone Panel.

I appreciate the Subcommittee on Environment addressing the important topic of "Improving EPA's Scientific Advisory Process" and holding this hearing. I view this topic as part of a much bigger picture – <u>how do we move the economy of the USA forward building on this nation's remarkable pool of scientific talent?</u>

Let me provide some context for this statement. Last week at the Society of Toxicology meeting in San Antonio, TX, a senior EPA scientist/manager asked a question as to what were the most important factors influencing human health. I suspect he was interested in which of the

myriad of risk factors with relative risks of a few percentage points increases over background risk based on air quality a few decades ago deserved more research. My answer was simple – in my opinion, the single most important risk factor for the health of the U.S. citizens and other populations around the world is SOCIO-ECONOMIC STATUS (SES). Jobs and income matters! A study by Steenland et al (2004) showed the mortality ratio for all-cause mortality for men in the lowest quartile of SES over the top quartile is 2.02. In other words, a doubling of the mortality rate for individuals in the lowest quartile of SES versus those in the top quartile. Putting it another way, moving from the bottom quartile to the second quartile reduced the mortality ratio to 1.69 and a move from the second to the third quartile reduced the mortality ratio to 1.25. If the USA wants to improve the health of Americans we need to create employment – JOBS.

Some individuals reading this may argue that I am off track relative to the topic subject of this hearing. I am on track – let me explain.

The USA has a remarkable pool of scientific and engineering talent. We have excellent colleges and universities that attract students from around the world, including the world's most rapidly advancing economy – China. Historically, well-educated individuals have found an abundant of job opportunities in the USA. Indeed, many students who came from abroad elected to stay in the USA for the opportunities it afforded. The current job market for professionals in the USA is the softest I have seen during my professional career. I am optimistic the situation can change, however, major change will require many small and seemingly insignificant changes.

One change that is required is to start using ALL of the USA's scientific and engineering talent as candidates to serve as members or consultants on Scientific Advisory Committees such as those assembled by the EPA. In the past, EPA's scientific advisory committees have been composed largely of academic scientist and engineers. Using information from the EPA's SAB website I note that 41 of the 46 members of the chartered SAB are from academic institutions and 87 of the 110 members of seven standing committees are from academic institutions. I know many of these academicians personally; they are first-rate scientists or engineers. Do they represent the best and brightest of all the scientists and engineers in the USA? The answer cannot be Yes since that would mean the millions of scientists and engineers employed in the private sector somehow do not measure up. Baloney!

Some will quickly note that those in the private sector have financial conflicts of interest that preclude their service on EPA Advisory Committees because of requirements of the Federal Advisory Committee Act (FACA). If FACA is used to deny the EPA of the talents of individuals from the private sector, then I think the solution is quite simple – Congress should change FACA. Some academic scientists and EPA managers would argue that individuals in the private sector are biased – their primary motivation is making certain their employer stays profitable. I am glad they have that motivation, it is important. It is consistent with the best interests of the USA. I have worked with many private sector firms and employees. I can assure you they understand the importance of getting the science right to ensure long-term profitability. I am tired of some scientists telling me that the actions of the U.S. Tobacco industry are proto-typical of all U.S. industry. That statement is clearly false.

One might ask why it is important to broaden the talent pool for service on EPA Advisory Committees. One good reason is context. EPA's scientific committees deal with complex issues, not abstract scientific facts, but science interpreted in the context of complex issues. The question is not just whether a chemical or technology is hazardous, but, also how can the use of the chemical be changed or the technology advanced to reduce health hazards and increase efficiency and effectiveness. Private sector scientists and engineers deal with these concepts daily and could bring the concepts to bear in Committee discussions. Everyone wins when all participants contribute to the dialogue and everyone takes something home to their university or private sector job.

In preparation for this hearing I reviewed the SAB website to determine the status of formation of several new committees. I found lists of nominees for two committees – "Hydraulic Fracturing Potential Impacts on Groundwater Resources" and "Polychlorinated Biphenyls (PCBs) Review." I noted that there were 144 nominees for the "Fracturing Panel" and 55 nominees for the PCB Panel. I was encouraged that the "Hydraulic Fracturing" nominees included a number of individuals employed in the private sector, including many with real-world experience in hydraulic fracturing. This is encouraging since I am aware of groups that have addressed health concerns of hydraulic fracturing without anyone on the Committee ever having visited a hydraulic fracturing site. I will be following with interest EPA's announcement of the composition of the final committee. I do hope it includes individuals from the private sector and environmental NGOs to complement the academic appointees. Moreover, I hope that the first meeting includes a visit to a hydraulic fracturing site with the committee members putting on fire retardant clothing, steel-capped boots and other protective gear as they learn what "hydraulic fracturing" is all about. I am confident everyone will learn something new!

Beyond that first meeting I hope that the remaining hydraulic fracturing committee meetings will be face-to-face meetings. This is important for committee members to get to know their fellow committee members and, moreover, face-to-face meetings encourage public participation. I hope that at least one-third of the time at each meeting is reserved for public comment and dialogue. I strongly discourage the use of "Tower of Babel" teleconferences. If a topic warrants assembling a Committee, it warrants face-to-face meetings of the Committee.

As the Committee proceeds with its deliberations I strongly encourage the use of both written and oral communications in which <u>every</u> committee member clearly states their scientific views on the topic at hand. If the topic is outside their professional expertise, they should note that. In my opinion, consensus views are fine for religious, labor and political assemblies. Science is best served by examining all facets of a scientific issue and making certain all of the nuances are explored and covered in the Committee's final communication to the Administrator and the public.

The PCB review activity noted earlier is part of the Agency's on-going Integrated Risk and Information System (IRIS). The Agency's IRIS activities are currently being revitalized with new leadership from Dr. Ken Olden. In my view that revitalization is long overdue and Dr. Olden has it on the right track. I learned earlier this week that the activities of the proposed PCB committee may be handled as a Subcommittee or Panel of the Chemical Assessment Advisory

Committee. However the Committee is assembled, I do hope that it will include an appropriate number of individuals from the private sector.

In conclusion, I want to emphasize the comments I have offered are my own personal views. They do not necessarily represent the views of any public or private organizations I have advised.

I will be pleased to address any questions you may have now or wish to forward to me.

ATTACHMENT 1

BIOGRAPHY

ROGER O. McCLELLAN, DVM, MMS, DSc (Honorary),
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ROGER O. McCLELLAN serves as an advisor to public and private organizations on issues concerned with inhalation toxicology, comparative medicine, and human health risk analysis focusing on issues of air quality in the ambient environment and work place. He has over three decades of experience studying the human health hazards of exposure to diesel exhaust and promoting advances in diesel technology to minimize any health hazards. He received his Doctor of Veterinary Medicine degree with Highest Honors from Washington State University in 1960 and a Master of Management Science degree from the University of New Mexico in 1980. He is a Diplomate of the American Board of Toxicology and the American Board of Veterinary Toxicology and a Fellow of the Academy of Toxicological Sciences.

He served as Chief Executive Officer and President of the Chemical Industry Institute of Toxicology (CIIT) in Research Triangle Park, NC from 1988 through 1999. CIIT continues today as The Hamner Institute for Health Sciences. During his tenure, the organization achieved international recognition for development of scientific information under-girding important environmental and occupational health decisions and regulations. Prior to his CIIT appointment, Dr. McClellan was Director of the Inhalation Toxicology Research Institute, and President of the Lovelace Biomedical and Environmental Research Institute, Albuquerque, New Mexico. The Institute continues today as a core element of the Lovelace Respiratory Research Institute. During 22 years with the Lovelace organization, he provided leadership for development of one of the world's leading research programs concerned with the health hazards of airborne radioactive and chemical materials. Prior to joining the Lovelace organization, he was a scientist with the Division of Biology and Medicine, U.S. Atomic Energy Commission, Washington, DC (1965-1966), and Hanford Laboratories, General Electric Company, Richland, WA (1959-1964). In those assignments, he conducted and managed research directed toward understanding the human health risks of internally deposited radionuclides.

Dr. McClellan is an internationally recognized authority in the fields of inhalation toxicology, aerosol science, comparative medicine, and human health risk analysis. He has authored or co-authored over 350 scientific papers and reports and edited 10 books. In addition, he frequently speaks on risk assessment and air pollution issues in the United States and abroad. He is active in the affairs of a number of professional organizations, including past service as President of the Society of Toxicology and the American Association for Aerosol Research. He serves in an editorial role for a number of journals, including service since 1987 as Editor of Critical Reviews in Toxicology. He serves or has served on the Adjunct Faculty of 8 universities.

Dr. McClellan has served in an advisory role to numerous public and private organizations. He has served on senior advisory committees for the major federal agencies concerned with human health. This included services as past Chairman of the Clean Air Scientific Advisory Committee, Environmental Health Committee, Research Strategies Advisory Committee, and Member of the Executive Committee, Science Advisory Board, U. S. Environmental Protection Agency; Member, National Council on Radiation Protection and Measurements; Member, Advisory Council for Center for Risk Management, Resources for the Future; Member, Health Research Committee, Health Effects Institute; and service on National Academy of Sciences/National Research Council Committees on Toxicology (served as Chairman for 7 years), Risk Assessment for Hazardous Air Pollutants, Health Risks of Exposure to Radon, Research Priorities for Airborne Particulate Matter, as well as the Committee on Environmental Justice of the Institute of Medicine. He has served on the Board of Scientific Councilors for the Center for Environmental Health Research of the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry and on the National Institutes of Health Scientific Advisory Committee on Alternative Toxicological Methods. He currently serves on the National Aeronautics and Space Administration Lunar Airborne Dust Toxicity Advisory Group.

Dr. McClellan's contributions have been recognized by receipt of a number of honors, including election in 1990 to membership in the Institute of Medicine of the National Academy of Sciences. He is a Fellow of the Society for Risk Analysis, the American Association for Aerosol Research, the Health Physics Society, and the American Association for the Advancement of Science. In 1998, he received the International Achievement Award of the International Society of Regulatory Toxicology and Pharmacology for outstanding contributions to improving the science used for decision making and the International Aerosol Fellow Award of the International Aerosol Research Assembly for outstanding contributions to aerosol science and technology. In 2002, he was inducted into the University of New Mexico Anderson School of Management Hall of Fame for contributions to the effective management of multi-disciplinary research organizations. He received the Society of Toxicology Merit Award in 2003 for a distinguished career in toxicology and the Society's Founders Award in 2009 for contributions to science-based safety/risk decision-making. In 2012, he received the Outstanding Career Achievement Award of the International Dose-Response Society for contributions to understanding dose-response relationships and the David Sinclair Award of the American Association for Aerosol Research for sustained excellence in aerosol research and technology.

In 2005, The Ohio State University awarded him an Honorary Doctor of Science degree for his contributions to comparative medicine and the science under-girding improved air quality. In 2006, he received the New Mexico Distinguished Public Service Award. In 2008, Washington State University presented Dr. McClellan the Regents Distinguished Alumnus Award, the highest recognition the University can bestow on an Alumnus.

Dr. McClellan has a long-standing interest in environmental and occupational health issues, especially those involving risk assessment, and air quality and in the management of multidisciplinary research organizations. He is a strong advocate of science-based decision-making and the need to integrate data from epidemiological, controlled clinical, laboratory animal and cell studies to assess human health risks of exposure to toxic materials and to inform policy makers in developing standards and guidance to protect public health.

BIOGRAPHY

Roger O. McClellan, DVM, MMS, DSc (Honorary),
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Roger O. McClellan is an advisor to public and private organizations on inhalation toxicology and human health risk analysis issues. He received a Doctor of Veterinary Medicine degree with Highest Honors from Washington State University (1960). He is a Diplomate of the American Board of Toxicology and the American Board of Veterinary Toxicology and a Fellow of the Academy of Toxicological Sciences, American Association for Advancement of Science, Society for Risk Analysis and American Association for Aerosol Research.

He is an internationally recognized authority in the fields of inhalation toxicology, aerosol science and human health risk analysis. He has over 3 decades of experience studying the human health hazards of exposure to diesel exhaust. He is well known for the leadership he provided to the Lovelace Inhalation Toxicology Research Institute (1966-1988) in Albuquerque, NM and the Chemical Industry Institute of Toxicology (1988-1999) in Research Triangle Park, NC. Both organizations are internationally recognized for their research on the mechanisms of action of pollutants and assessing human health risks. He has authored over 300 scientific papers and reports and edited 10 books. He is a Past President of the Society of Toxicology and the American Association for Aerosol Research. He serves in an editorial role for a number of journals, including continuing service as Editor of Critical Reviews in Toxicology. He serves or has served on the Adjunct Faculty of 8 universities.

McClellan has served in an advisory role to numerous public and private organizations including service on senior advisory committees for 8 federal agencies and on many committees of the National Academy of Sciences/National Research Council. He is past Chairman of U.S. EPA's Clean Air Scientific Advisory Committee and served on Panels that have reviewed the National Ambient Air Quality Standards for all of the Criteria Pollutants.

McClellan's contributions have been recognized by receipt of a number of honors. He was elected in 1990 to membership in the Institute of Medicine of the National Academy of Sciences. In 2005, The Ohio State University awarded him an Honorary Doctor of Science degree for his contributions to the science under-girding improved air quality. In 2008, Washington State University presented him the Regents Distinguished Alumnus Award, the highest recognition the University can bestow on an alumnus. He is a strong advocate of risk-based decision-making integrating information from epidemiological studies, clinical investigation, laboratory animal bioassays and mechanistic studies using molecules, cells, tissues and intact mammals.

Chairman STEWART. Thank you, Dr. McClellan.
Ma'am, Dr. Grifo.

**TESTIMONY OF DR. FRANCESCA GRIFO,
SENIOR SCIENTIST AND SCIENCE POLICY FELLOW,
UNION OF CONCERNED SCIENTISTS**

Dr. GRIFO. Good morning, Chairman Stuart and Ranking Member Bonamici. Thank you for the opportunity to share my concerns regarding the proposed amendments to the ERDDA, or the Environmental Research, Development, and Demonstration Authorization Act of 1978. The changes described in the amendments I believe would slow down the work of the EPA's Science Advisory Board—which I will refer to as SAB—remove long-standing and widely accepted practices for dealing with conflicts of interest, and reduce expertise.

Congress articulated broad requirements for balance, independence, and transparency in the Federal Advisory Committee Act. FACA instructs agencies to ensure committees will not be inappropriately influenced by special interests. Currently, all the members of EPA's SAB are appointed as Special Government Employees and subject to most of the government's ethics rules. They are required to report information about income, activities, assets, liabilities—it is quite a long list—and to answer questions regarding causes for impartiality and previous involvement and public statements on issues under consideration.

Conflict of interest applies to financial interest; bias applies to intellectually or ideologically motivated points of view. They are different. Conflict of interest should be eliminated. Bias should be managed by appointing a committee such that a balance of perspectives is achieved except for when a perspective is far from the mainstream or the individual is unable to consider other points of view. It is important to collect sufficient information from candidates and obtain public input so that the designated Federal officials can make their best determinations on these issues.

On to a couple of provisions in the discussion draft. Inserting risk or hazard assessment in ERDDA expands the scope of the SAB's work to potentially include every risk or hazard assessment proposed by the Agency. This would overwhelm already limited resources and delay assessments. When these assessments can, when necessary, be reviewed by other means, why add this?

Holding a public information gathering session before major advisory activities to discuss the state of related science will consume time and resources. Since the SAB meetings are open to the public with time set aside for their oral comments, the Board accepts the written comments and will be discussing the state of the science, what value does this add?

Requiring SAB to respond in writing to public comments is a burden and distraction given that special interests could arrange to have thousands and thousands of comments submitted every week. Since committees read and respond to written public comments in the final report content and to oral comments during the proceedings, what does this add?

If persons affiliated with entities that may have a potential interest in the Board's activities are not excluded from the Board but

simply required to fully disclose the conflict, the objectivity of an advisory committee and the public's trust and the advice rendered are irrevocably damaged. Scientists are not immune to influence by their financial prospects conflicted experts can influence panel decisions by their voting, by dominating the discussion, and by pressuring other panelists. Disclosure of individual and institutional financial relationships is a critical but limited first step. Disclosure does not resolve or eliminate conflicts. When a scientist has irreplaceable expertise but has a conflict, that expert can be invited to present to the committee without serving on the committee.

The provision requiring that at least ten percent of the membership of the Board be from state, local, or tribal governments sounds like stakeholder representation and could be interpreted to mean that these members of the SAB would be appointed as representatives rather than Special Government Employees and they would not be subject to most of the government ethics rules and hence able to serve without disclosure of conflicts of interest. There are reports from the Government Accountability Office, Bipartisan Policy Center, and Keystone all state that members of committees that consider scientific and technical issues should be appointed as Special Government Employees.

If experts cannot participate in the advisory activities that potentially involve review of their own work, even if their work is one of hundreds of studies under consideration, some specialized experts would be disqualified. Standard practice among Federal agencies and the National Academies is to recuse scientists from peer review of their own work but allow those scientists to serve on the committee.

Just a couple of—four quick recommendations. The Bipartisan Policy Center report and Keystone report have extensive recommendations so I am just going to go through four that I believe are critical. All Federal scientific advisory panels and subcommittees, including those put together or managed by contractors, should be subject to FACA and have all members appointed as special government employees.

The goal of agencies should—two, the goal of agencies should be to appoint only panelists who do not have conflict of interest. This is reinforced in the Bipartisan Policy Center report as well as the Keystone report. And agencies should select panel members based on their expertise and on their ability to contribute to the panel deliberations without conflict of interest or undue bias, again, Bipartisan Policy Committee and Keystone.

Waivers should be publicly available and only issued as rare, temporary exceptions, and panelists with waivers should not be allowed to serve in leadership positions.

And finally, panel chairs should remind panelists at every meeting to disclose new or previously undisclosed information relevant to determining conflict of interest or bias.

Thank you and I will be happy to answer questions.

[The prepared statement of Dr. Grifo follows:]

Union of Concerned Scientists
Citizens and Scientists for Environmental Solutions

Testimony of Francesca T. Grifo, Ph.D.
Senior Scientist, Science Policy Fellow, Union of Concerned Scientists
Before the Subcommittee on the Environment,
Committee on Science, Space, and Technology,
U.S. House of Representatives
Hearing on "Improving EPA's Scientific Advisory Processes"
March 20, 2013

Thank you for the opportunity to share my concerns regarding the proposed discussion draft of amendments to the Environmental Research, Development, and Demonstration Authorization Act of 1978 (ERDDA). I want to begin by clarifying that while I will refer to and have contributed to both *"Improving the Use of Science in Regulatory Decision-Making: Dealing with Conflict of Interest and Bias in Scientific Advisory Panels, and Improving Systematic Scientific Reviews." released late last year by the Keystone Center, and "Improving the Use of Science in Regulatory Policy"* published by the Bipartisan Policy Center in 2009, my testimony is my own and in no way should be construed as an official representation of either report.

The changes to ERDDA as described in the discussion draft will slow down the work of the EPA Scientific Advisory Board, remove long standing and widely accepted practices for dealing with conflicts of interest (COI), reduce the expertise of SAB members, and do nothing to increase the transparency of its workings or results. Over the last decade, a great deal of attention has been paid to the improvement of federal scientific advisory committees. There are recommendations in the Bipartisan Policy Center report (Boehlert 2009), Keystone report (Keystone 2012), at least ten GAO reports (especially GAO 2001, 2004, 2008, 2009), a study by the Institute of Medicine Board on Health Science Policy (IOM 2009), the EPA Office of the Inspector General (USEPA 2009), and in the 2010 OSTP scientific integrity memorandum (Holdren 2010). This testimony is comprised of a brief discussion of the EPA SAB, a critique of the draft legislation under discussion, and recommendations distilled from the aforementioned reports.

The FEDERAL ADVISORY COMMITTEE ACT AND EPA's SCIENTIFIC ADVISORY BOARD

The Federal Advisory Committee Act (FACA) of 1972 (PL 92-463) created a process for convening, operating, and terminating federal advisory committees that provide advice to the Executive Branch. In the act, Congress articulated broad requirements for balance, independence, and transparency. It is very important to note two distinct committee roles. The first is to advise the Government based on the exercise of their own individual best judgment on behalf of the Government i.e. to discuss and deliberate in a way that is free from conflicts of interest, providing independent advice. The second is to provide consensus among various identified interests or

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stakeholders. This matters because the members of committees created to provide independent advice are appointed as "Special Government Employees" (SGEs) and are subject to most of the Government's ethics rules (USOGE 2008). Members appointed as "Representatives" are not subject to this oversight and are expected to provide committees with the points of view of a recognizable group of persons. FACA instructs agency officials to ensure the committees will not be inappropriately influenced by any special interests and to appoint members accordingly.

Currently all the members of EPA's SAB are appointed as SGEs (USGSA 2013). Therefore all members of the SAB are subject to most of the Government's ethics rules. In a practical sense this means they must fill out an OGE form 450 as well as EPA Form 3110-48. Both of these forms ask for a variety of information about employment, consulting, honoraria and volunteer work, compensated expert testimony, research support, assets, liabilities, agreements or arrangements, gifts, travel reimbursements, and additional questions regarding other reasons for any impartiality, previous involvement and public statements on the issues under consideration.

While FACA is an excellent basis for the management of advisory committees it is important to note that decisions of the courts have created four loopholes in FACA that need to be closed. These are a contractor loophole that makes it easy for agencies to avoid FACA by hiring private contractors to organize and operate an advisory committee, the strict management loophole that makes it possible for agencies to let a regulated entity appoint committee members and share joint control of the agenda, the subcommittee loophole under which an agency can avoid transparency and balance requirements of FACA by assigning work to subcommittees, and finally, under the non-voting participant loophole, outsiders can take an active role in Government committees without the committee becoming subject to FACA so long as the outsiders do not vote on issues before the committee.

Although FACA somewhat lumps them together, COI and bias are two completely different concepts and both the information required of a potential panel member and how that information is applied to assessing bias and COI need to be quite different as well. COI applies to financial interests of an expert as well as to others with whom they share a common financial interests. Bias relates to intellectually or ideologically motivated points of view. COI should be eliminated. Bias should be managed by appointing members of a committee such that a balance of perspectives is achieved except for when a perspective is unreasonably far from the mainstream or the individual is totally unable or unwilling to consider other points of view. Then it might be wise to not appoint that particular expert. There are rarely bright lines. That is why it is important to collect sufficient information from potential candidates and offer opportunities for input from the public so that the designated federal officials together with agency ethics officers can make their best determinations regarding both COI and bias.

PROVISIONS IN THE DISCUSSION DRAFT WOULD SLOW THE WORK OF EPA's SAB

The discussion draft would slow the work of EPA's SAB in three ways: broadening the scope of the committee, adding additional meetings, and requiring written responses to significant public comments. The draft would insert "risk or hazard assessment" at three places in ERDDA. This appears to expand the scope of the SAB's work to include every risk or hazard assessment proposed by the agency. This represents a large and unnecessary expansion of responsibilities. The board's current scope is already quite large and it is hard to see how this would do anything but overwhelm already limited resources and both add years to these assessments and make the board less effective and certainly slower overall. It is hard to see how this adds value when these risk and hazard assessments can, when necessary, be reviewed by other means.

The discussion draft would also require that prior to conducting major advisory activities, the Board hold a public information-gathering session to discuss the state of the science related to the advisory activity. Since the SAB meetings are open to the public with time set aside for public oral comments, the Board accepts written public comments, and will be discussing the state of the science many times, it is hard to see the value added by this provision. Instead it appears that this is another delay tactic that would take precious resources away from the work of the committee.

Finally, while the SAB has always encouraged, read and acted on public comments, including oral comments and discussion during the proceedings, they would now be required to respond in writing to significant comments offered by the public. This is a very large burden and distraction, making it necessary for the Board to offer endless opportunities for such input and taking limited resources away from the work of the committee to fix a problem that does not exist. It is generally accepted that the committees have been responsive to public comments without having to do so in writing (Beinecke et al 2012 and Benjamin et al 2012).

Such a slowdown leading to even longer delays in regulation harms both citizens and businesses (CSS 2011). The failure to release health and safety rules obviously leaves families, workers and consumers unprotected. But it also costs businesses money through the general toll of regulatory uncertainty, increased health costs from sick workers and lost billions as consumer anxieties rise when they are faced with tainted food and dangerous products.

CONFLICT OF INTEREST

Conflicts of interest threaten the integrity of science. Specifically, the objectivity of the members of an advisory committee and the public's trust in the advice rendered by that committee are damaged when a member of an advisory committee has a secondary interest that creates a risk of undue influence on decisions or actions affecting the matters in front of the committee. The scientific experts who advise the Government should reflect the best minds in America, possessing comprehensive, independent and up-to-date knowledge. Although other interests may inappropriately

influence advisory board member behavior, financial interests are easily identified and regulated.

Scientists are not immune to having their work and conclusions influenced by their financial prospects. Several recent meta-analyses found that scientists with conflicts of interest publish scientific findings that are more supportive of their interests, (or those of their funders) than other reports in the literature. Conflicted scientific conclusions have been found to be biased relative to the broader literature on the safety of various drugs, second-hand tobacco smoke, the health effects of soda consumption, and other topics. This is commonly known as the "funding effect," (Michaels 2008) and its prevalence and seriousness prompted the editors of thirteen major biomedical journals (including *NEJM* and *JAMA*) in 2001 to stop publishing studies done under contracts allowing sponsors to control the research findings (Davidoff et al. 2002). Similar restrictions on research information used in regulation have been proposed (Michaels and Wagner 2003). Experts on advisory committees with conflicts of interest can influence panel decisions in multiple ways, not only by voting but also by dominating the discussion and pressuring other panelists.

In 2009, the Institute of Medicine did an exhaustive report entitled *Conflicts of Interest in Medical Research, Education and Practice*. The IOM (IOM 2009) observed that

> *"concerns are growing that wide-ranging financial ties to industry may unduly influence professional judgments involving the primary interests and goals of medicine. Such conflicts of interest threaten the integrity of scientific investigations, the objectivity of professional education, the quality of patient care, and the public's trust in medicine."*

The goal of conflict of interest policies should be to protect the integrity of the professional judgment and to preserve the public trust. Disclosure of individual and institutional financial relationships is a critical but limited first step. Disclosure does not resolve or eliminate conflicts. The designated federal officers must then evaluate and act upon the disclosed information.

The draft contains a series of disclosure requirements that would upend widely accepted practice for limiting COI.

> "Persons with substantial and relevant expertise are not excluded from the Board due to affiliation with or representation of entities that may have a potential interest in the Board's advisory activities, so long as that interest is fully disclosed to the Administrator and the public;" (Discussion Draft)

This means that an individual who works for a company who has a chemical or product being reviewed by an advisory committee could still serve on the committee and even vote so long as they work on a slightly different chemical or product, have relevant expertise and the conflict is reported. This will not increase the public trust, protect

the integrity of the SAB, increase the objectivity of the panel's deliberations, nor reduce the influence of that company on the professional judgment of that individual. This is contrary to the current operations of the National Academies, IARC, and many other scientific bodies. I acknowledge that industry scientists bring relevant expertise and experience and I suggest that when a scientist has irreplaceable and necessary expertise, but is affiliated with or represents an entity that may have a potential interest in the Board's advisory activities, that the expert be invited to present to the committee but not to actually serve on the committee.

One notable and notorious example of how COI can influence outcomes is the EPA's consideration of hexavalent chromium - the chemical made famous in the Oscar-winning film *Erin Brockovich*. Full details of this complex story have been recently revealed in a series of articles and video created by the Center for Public Integrity and the NewsHour (Heath and Greene 2013, Heath 2013, and O'Brian 2013).

The discussion draft also contains a provision requiring that at least 10% of the membership of the Board be from State, local, or tribal governments. While there is no inherent reason why scientists from State, local or tribal governments could not have the needed technical expertise to serve on the SAB, this sounds like stakeholder representation that could be misconstrued to mean that these members of SAB would be appointed as "Representatives" and not as SGEs, thus losing the requirement that they are subject to most government ethics rules and hence able to serve without any investigation of conflicts of interest. SAB asks its members to advise the Government based on the exercise of their own individual best judgment on behalf of the Government i.e. to discuss and deliberate in a way that is free from conflicts of interest or to provide independent advice. GAO has written extensively that while some FACA committees at EPA legitimately include representatives of various stakeholders, members of SAB and other committees that consider scientific and technical issues should be appointed as SGEs (GAO 2001, 2004, 2008, 2009).

REDUCING THE EXPERTISE OF SAB SCIENTISTS

The questions brought to the SAB are complex. EPA needs to have scientists with the deepest and most direct expertise possible. The discussion draft would not allow experts to "participate in advisory activities that directly or indirectly involve review and evaluation of their own work" even if their work is one of hundreds of relevant studies. This would disqualify some of the most specialized experts and many committees would instead engage experts whose scientific work is either tangential or unrelated to the committee's deliberations. Currently most federal agencies recuse scientists from any decisions that either directly or indirectly influence the outcome of funding decisions or from participating in peer review of their own work and the work of their collaborators. This works well at the National Academies, the National Institutes of Health, the National Science Foundation, and a host of other federal agencies including EPA.

LINE-BY-LINE CRITIQUE OF THE DISCUSSION DRAFT

SEC.2. SCIENCE ADVISORY BOARD.
"(2)(A) the scientific and technical points of view represented on and functions to be performed by the Board are fairly balanced among the members of the Board"

- This language is redundant and unnecessary. The Federal Advisory Act (FACA) already says this.

"(2)(B) at least ten percent of the membership of the Board are from State, local, or tribal governments"

- This is a science advisory board. The Office of Government Ethics and the GAO state that when members are acting to advise the government they are not stakeholders. BPC and Keystone stress that members of scientific advisory boards are to be appointed as SGEs not stakeholders.
- It is not clear what problem this is intended to fix or how this would enhance the scientific credentials or expertise of the SAB.

"(2)(C) persons with substantial and relevant expertise are not excluded from the Board due to affiliation with or representation of entities that may have a potential interest in the Board's advisory activities, so long as that interest is fully disclosed to the Administrator and the public;

- Overturns generally accepted practice of reducing, removing or creating a waiver to manage conflicts of interest.
- This undermines the public's trust in the EPA and its SAB.

"(2)(E) Board members may not participate in advisory committees that directly or indirectly involve review and evaluate their own work".

- The National Academies, the National Institutes of Health and the National Science Foundation address this through recusal. It is not necessary to eliminate scientists with the closest expertise to the issue under deliberation form the panel entirely.
- The Research Integrity Roundtable (RIR) (Keystone 2012) states "Caution must be exercised to ensure that panel members are not engaged in evaluating their own work as a central part of a scientific review." Note the inclusion of "as a central part". As a participant in the RIR deliberations leading to this report, I took this to mean that if the work of an expert is one of some 50 or 70 articles being looked at, that could be dealt with through recusal rather than elimination of that expert from the pool of panel candidates.

"(3)(D) require that upon nomination, nominees shall file a written report disclosing financial relationships and interests, including Environmental Protection Agency grants, contracts, cooperative agreements, or other financial assistance, that are relevant to the Board's advisory activities for the three-year period prior to the date of their nomination,

- This information is already required to be disclosed going back two years by both the Office of Government Ethics and the EPA on forms OGE form 450 as well as EPA Form 3110-48. Both BPC (Boehlert 2009) and RIR (Keystone 2012) support a two year look back "when considering whether a conflict of interest exists".

"(3)(D) continued: and relevant professional activities and public statements for the five-year period prior to the date of their nomination;

- This information is already required without a time limit designated. This information would be important in considering bias and hence a five year period seems short. RIR (Keystone 2012) suggests a CV which would include relevant professional activities, testimony and publications "that go as far back in time as is reasonably possible but in all cases, at least 5 years."
- Both RIR and BPC states the following regarding professional activities "going back five years. Members should also be asked to disclose, to the best of their ability, any relevant professional activities that occurred more than five years prior to their committee service."

"(3)(E) make such reports public, with the exception of dollar amounts, for each member of the Board upon such member's selection.

- RIR suggests "the agency should post...the CVs of proposed panelists and any waivers for COI on the agency's website and allow for public comment on the appropriateness of the panelists."

"(4)(b) (1)(A) and (B) and (2) (A) - three insertions of "risk or hazard assessment"

- Potentially broadens the scope and duties of EPA's SAB at a time when resources are being reduced leading to dilution and delay of efforts.

"(4)(d)(2) Prior to conducting major advisory activities, the Board shall hold a public information-gathering session to discuss the state of the science related to the advisory activity.

- Since the SAB meetings are open to the public with time set aside for public oral comments, the Board accepts written public comments, and will be discussing the state of the science many times, it is hard to see the value added by this provision. Instead it appears that this is another delay tactic that would take precious resources away from the work of the committee.

"(4)(d)(4) The administrator and the Board shell encourage public comments, including oral comments and discussion during the proceedings, that shall not be limited by an insufficient or arbitrary time restriction. Public comments shall be provided to the Board when received. The Board shall respond in writing to significant comments offered by members of the public."

RECOMMENDATIONS

EPA's Science Advisory Board has been the object of much attention from Congress through the GAO. Starting in 2001 GAO has released at least 10 products that to some degree make recommendations to improve advisory committees at the EPA. It is noteworthy that in 2009 a statement by John Stephenson notes the following:

> "EPA has been responsive to our 2001 recommendations for improving the balance and independence of committees convened by EPA's Science Advisory Board by developing policies and procedures that represent best practices. As a result, if these policies and procedures are implemented effectively, EPA can have an assurance that its Science Advisory Board panels are independent and balanced as a whole."

Certainly this is a good place to start. Both the BPC report and RIS have extensive recommendations. Here is a subset I believe are critical to further improvement.

1. All federal scientific advisory panels and subcommittees, including those put together or managed by contractors, should be subject to FACA and have all members appointed as SGEs.

2. The goal of agencies should be to appoint only panelists who do not have conflicts of interest. (Keystone 2012 and Boehlert 2009)

3. Waivers should be issued as a rare exception with the premise that over time panelists with waivers would be replaced by experts without any COI.

4. Panelists with waivers should not be allowed to serve as panel chairs or in any other leadership position.

5. The chair of the panel, or the convening authority's designated staff member should actively track and manage waivers and recusals and make sure recusals take place when necessary.

6. Panel chairs should remind panelists at every panel meeting of their ongoing duty to disclose any new or previously undisclosed information relevant to determining conflict of interest.

7. Agencies should select scientific advisory panel members based on their expertise, experience, and on their ability to contribute to the panels deliberations without COI or undue bias. (Keystone 2012)

8. Except when specifically prohibited by law, agencies should make all Conflict of Interest Waivers granted to committee members publicly available. (Holdren 2010)

9. All reports, recommendations, and products produced by SAB should be treated as solely the findings of the committee rather than of the US Government and thus are not subject to intra- or inter-agency revision. (Holdren 2010)

10. While still collecting all the necessary information on panelists and their immediate families over the number of years designated in Keystone, the OGE and GSA should work on ways to centralize reporting to minimize the burden on panel candidates.

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*** BUT NOT REPORDUCED THEREIN**

Francesca T. Grifo
Senior Scientist and Science Policy Fellow

As a senior scientist and science policy fellow at the Union of Concerned Scientists (UCS), Francesca Grifo undertakes research on US federal agency use of science in decision-making, conducts oversight of federal implementation of Scientific Integrity Policies and advises the UCS Center for Science and Democracy on scientific integrity.

Dr. Grifo came to UCS in 2005 from Columbia University where she directed the Center for Environmental Research and Conservation graduate policy workshop and ran the Science Teachers Environmental Education Program. Prior to that, she was director of the Center for Biodiversity and Conservation and a curator of the Hall of Biodiversity at the American Museum of Natural History in New York. Dr. Grifo edited and contributed to the books *Biodiversity and Human Health and The Living Planet in Crisis: Biodiversity Science and Policy.* In addition to her scholarly work, Dr. Grifo was the manager of the International Cooperative Biodiversity Groups Program at the National Institutes of Health. She was also a senior program officer for Central and Eastern Europe for the Biodiversity Support Program, a consortium of the World Resources Institute, the Nature Conservancy and the World Wildlife Fund. She also served as AAAS Fellow in the Office of Research at the U.S. Agency for International Development.

Dr. Grifo earned a doctorate in botany from Cornell and a bachelor's degree in biology from Smith College.

Dr. Grifo has testified before Congress on the subject of scientific integrity in federal policy making and is widely quoted on the topic in media outlets such as *The New York Times, Washington Post,* and National Public Radio.

Chairman STEWART. Once again, I would like to thank the witnesses for being available for questioning today and we look forward to hearing your responses to some of our concerns.

Committee rules limit questioning to five minute rounds alternating between Republicans and Democratic Members of the Subcommittee. After all Subcommittee Members have asked questions, I ask unanimous consent to recognize Committee Members not on the Subcommittee.

Without objection, so ordered.

The Subcommittee Chair recognizes himself for five minutes to begin questioning.

I would like to kind of put this in historical perspective to get a larger view if we could. And let me begin with some things that I think will be just very easy to answer. I think we agree that it is important that our Scientific Advisory Panels be viewed as being fair and unbiased. That is the outcome that we are looking for here. We all would agree with that. That serves the American people, and frankly, it serves the EPA as well. And this shouldn't be a partisan issue and I don't think that it is a partisan issue.

And I think I would ask you, do you believe that the EPA's Boards, in the view of the public but also in the view of those entities in which they regulate, are they now viewed as being unbiased and arbitrary? Anyone who would like to just voice an opinion on that?

Dr. MCCLELLAN. Let me start by saying I certainly endorse your issue in terms of starting with a bipartisanship. As I look around the room at the portraits here, I think I testified before a number of those fine persons and both parties. So it is not a partisan issue, and I would further say that I have known many—hundreds of individuals who have served EPA in Advisory Committees. They are very talented individuals, and if you do the job well, it takes a lot of time.

Having said that, I don't think that the Committee has approached science always with a fair and balanced view. I think on many occasions individuals stumbled over their understanding of the science and the relationship to the policy. They are very quick to jump into the policy arena and advocate a lower standard or a specific nature of the standard which goes well beyond the issue of the science. So I think that distinction, it needs to be done better.

Chairman STEWART. Well, let me ask the question differently. I am asking something really quite simple, and that is that you think there is a growing perception, a growing concern among the public and among those entities that are regulated that the panels may not be as unbiased as we hoped they would be? That is a yes or no. Do you think there is a growing concern of that?

Dr. MCCLELLAN. Yes, there is.

Chairman STEWART. Yes——

Dr. MCCLELLAN. It is at all levels.

Chairman STEWART. Okay.

Dr. MCCLELLAN. I would say that goes from blue-collar workers that I meet in a mine or out in a fracking site in Wyoming to executives in——

Chairman STEWART. Okay. So a wide range. And Dr. Honeycutt, you seem to indicate yes. And Dr. Grifo?

Dr. GRIFO. Respectfully disagree.

Chairman STEWART. Okay. I would like to come back to that if I could, and I will. And then maybe just assuming that there is a growing perception problem, is this something that is relatively new? Ten years ago or 20 years ago was there more trust in this process? Did the people and the regulated agencies—did they feel like the advisory panels or advisory boards were giving better recommendations? Or is this something that has evolved in—you know, in more recent time? Again, a brief answer if you could because I would like to come back to you, Dr. Grifo, if we could.

Dr. MCCLELLAN. This is an issue that has really been there from the beginning. In my written testimony I recount my service as Chair of the ad hoc committee to review the first lead criteria document. So——

Chairman STEWART. So you think it has been a problem for a while?

Dr. MCCLELLAN. It has been a problem for a long period of time and a central part of the issue is mixing up science which should inform but not dictate policy. They are different.

Chairman STEWART. Okay. Dr. Honeycutt, would you agree or disagree?

Dr. HONEYCUTT. I would mainly agree with what you are saying.

Chairman STEWART. Okay. And either way, I think it is appropriate to recognize that there is a problem whether it has been recent or long-standing. It is time that we recognize that and try to address it through this legislation.

And Dr. Grifo, you respectfully disagreed. Would you expand on that a little bit?

Dr. GRIFO. I think we have a disagreement over the nature of the problem and the details, and I think we will probably get into that. I mean I am not going to sit here and say that every advisory committee is perfect. You know, they are not. But I do believe that they are—my problems with them are in a different direction than yours, I suspect.

Chairman STEWART. Okay. And that is fair. But I think we can agree that this process could be improved?

Dr. GRIFO. Always.

Chairman STEWART. Always, yes. There are concerns, whether they are recent or whether they are long-standing, there are concerns, and in my opinion, it is a growing concern having some background in this industry, in one industry that is regulated heavily by the EPA that there is a growing perception problem, and that is why this legislation is meaningful. That is why this is a great opportunity to address that because, once again, everyone is better served if there is a perception that this process is fair and that it listens to all opinions and all voices. I would like to pursue that, and maybe I will individually with you, but alas, my time is up.

So I will now turn to the time over to, again, the Ranking Minority Member.

Ms. BONAMICI. Thank you very much, Chairman Stewart. And thank you all for your testimony and for your years of work.

One of the things that I have heard frequently here in Congress is that we don't need new laws; we just need to enforce what we

have. So Dr. Honeycutt, in your testimony you said that you will hear others testify that EPA has ample guidance on conflict of interest, bias, and balance. The problem is they don't consistently follow it. So I am glad you recognize that or identify that as an issue.

As I mentioned in my opening remarks, I do hear from constituents who questioned the regulations and rules being promulgated by the EPA, and central to their concerns is the slow pace with which regulations are developed, implemented, and processes seem to slow down. And that is a concern that is expressed about other Federal agencies as well.

Because we hear so often in this era of what seems to be governing from one crisis to the next, what we are looking for is certainty in the communities, certainly the business community was to have certainty and stability to promote growth. So in that context, Dr. Grifo, based on your expertise and studying this issue, would the changes to EPA's Science Advisory Board under the legislation we are discussing today expedite or improve the EPA's process and receiving independent scientific advice?

Dr. GRIFO. In the amendments there are one or two things that I think are actually helpful, but I think the vast majority would have the long-term effect of slowing us down. And I think as you have rightly said, whether you are coming from a business perspective or, you know, a constituent-other-regular-people perspective, slowdown isn't good. I mean slowdown means that, you know, the regulations are slower, the health impacts continue, and so on, but it also means uncertainty for business and it also means that, you know, things happen. I mean if we don't do this right you end up with products on the market that are tainted or, you know, problematic, and that is not good for business either. So getting it right and doing it in a timely fashion is what I think we are all after.

Ms. BONAMICI. Thank you very much. And I know in your testimony you talked about one of the issues was this need to respond in writing to public comment, and I think you have effectively identified some of the problems that could come with that.

And I wanted to ask another question too. When a draft bill was introduced in the last Congress, it included the provision that would have limited the input of academic scientists to just ten percent of advisory panels, and I mentioned that is not in this current version of the bill. It is unclear why it was taken out, but this provision could be placed back in at some time. So I wonder if you could explain for the Committee what the impact of the science at the EPA would be if that were—type of provision were included in the final bill?

Dr. GRIFO. I think what is important—and we are conflating—are conflict of interest and bias. I think that what we need to really look at is getting committees that have no conflict of interest or very minimal and as a rare exception as the National Academies suggest. And really, you know, it is not about industry or not industry. It is about bias and conflict of interest. And I think we are going to find people with bias and conflicts in industry and in academia. And I think the point of submitting a lot of information, the point of having opportunities for public comment is to be able to allow the agencies—and there are really amazing people at the

agencies that spend enormous amounts of time doing the screening to get it right, to get the combination that is correct.

Ms. BONAMICI. Thank you. To your knowledge did either the Keystone Center or the Bipartisan Policy Center reports specifically recommend that there be more people from industry on advisory panels at the cost of reducing or eliminating some of the academic government-funded scientists?

Dr. GRIFO. No, absolutely not. And I should say, you know, it was rather an amazing and wonderful experience to be on the Keystone, that research integrity roundtable, because it was folks from academia, we had people from Baird, Dow, DuPont, American Chemistry Council, and when we sat around those tables and had those extended conversations—and we met off and on for 18 months—we agreed. We came together on the things that are in there. In the same way with the Bipartisan Policy Center, the name Bipartisan——

Ms. BONAMICI. Right.

Dr. GRIFO. —Policy suggests a broad input. And in fact, if you look at the list of those participants, they came from across the spectrum. And what we all agreed on was—I mean in both of these reports is that what is important is really looking at bias so that you get a balanced panel, conflict of interest so that you get a panel that minimizes or eliminates those conflicts.

Ms. BONAMICI. And just to follow up then, are the conflict-of-interest principles laid out in the draft bill we are discussing based on the recommendations of Keystone or the Bipartisan Policy Center?

Dr. GRIFO. No.

Ms. BONAMICI. Thank you very much. And I yield back. Thank you.

Chairman STEWART. Thank you.

Mr. Rohrabacher?

Mr. ROHRABACHER. Thank you very much, Mr. Chairman. And thank you for holding this very thought-provoking hearing today.

I would like to just read something from Dwight Eisenhower in his farewell address. Most people remember Eisenhower's admonition about the military-industrial complex, but they ignore what Eisenhower spent much more time warning us about in his farewell address, and I will read this portion of it. "The prospect of domination of the Nation's scholars by Federal employment project allocations and the power of money is ever-present and is gravely to be regarded. Yet, in holding scientific research and discovery in respect, we should, we must also be alert to the equal and opposite danger that public policy itself could become the captive of a scientific technological elites."

That is Dwight Eisenhower. Now, we almost never hear that quote but we hear the military-industrial complex all the time. I think that Eisenhower was a man of vision and a patriot in both of the areas where he warned us about. And in terms of what he was warning us about there, as I just read, the Congressional Research Service has done in the report, which you opened in your opening statement, Mr. Chairman, I would like to submit at this point that entire report for the record of this hearing.

Chairman STEWART. Without objection.

[The information appears in Appendix II]

Mr. ROHRABACHER. Okay. What the report found is that almost 60 percent of the members of EPA's chartered SAB and CASAC, that is 34 of the 58 members, have directly received National Center for Environmental Research Grants from the Agency since 2000. These advisors served as principal or co-investigators for EPA grants totaling roughly $140 million.

Now, what, unfortunately, we hear in situations like this, and we have talked about expertise and it can also be bias. Expertise is biased if those experts are from the private sector, but if those experts receive their experience by getting government grants and are part of government studies which have put them part of this elite that Eisenhower warned us about, now, that is a positive thing. All of a sudden that becomes experience.

And I think that we have got to pay attention to this because bias can result in cliques that are formed among people who make sure people in the clique get the research grants and are part of the system that determines public policy, which is exactly what Eisenhower was warning us against.

The research, of course, that we are talking about, example: four of seven members of the Clean Air Scientific Advisory Committee, which reviewed the EPA's Final Particulate Matter on the National Standards, have received million-dollar-plus EPA grants related to particulate matter since 2010. Now, if that isn't bias, I don't know. It is one thing to be able to have the scientific knowledge to judge what is going on, but to have already participated in research, that indicates a bias and something we need to address. And I would hope—and maybe I will. Doctor, maybe we should give you a chance to comment on what I have just stated, because obviously I am aiming this at the EPA.

Dr. GRIFO. Happy to, sir.

Mr. ROHRABACHER. Yes.

Dr. GRIFO. I think again that is not what I am saying. Bias matters; conflict of interest matters. Those are the things we need to examine. There are very well-equipped experienced folks in the agencies spending inordinate amount of time examining those things and coming to the best decisions they can with the guidance from the Office of Government Ethics, the General Services Administration, all those folks that are working on this. And I think what we are talking about are not necessarily including or excluding people because of the institutions that they work for. It is about what they turn in on those forms. And those forms are extraordinarily extensive. I mean if anything, they are—you know, they are very burdensome and long.

Mr. ROHRABACHER. But we do——

Dr. GRIFO. But it is the information that we need in order to bury carefully make those determinations.

Mr. ROHRABACHER. Well, Mr. Chairman—and obviously, the report that has been given to us by the Congressional Research indicates that we—that there are people who are in the clique who are getting these grants and then getting the jobs. And Eisenhower warned us about this, and quite frankly, we have seen evidence of that in a number of areas, especially in fracking and these other things that you mentioned.

Thank you very much for the hearing today.

Chairman STEWART. Yes, thank you, Mr. Rohrabacher.

Now, we turn to Ms. Edwards.

Ms. EDWARDS. Thank you, Mr. Chairman. And I just want to say, first, I had the privilege as the former Ranking Member of the Investigation and Oversight Subcommittee—and I can recall well the numerous questions about EPA's scientific integrity, and specifically, the concerns about the scientific advisory processes. And while I understand the concerns and those expressed by the witnesses today, I think the aims of the draft bill that is in front of us with it, it is not really clear to me that this bill and the sort of recommended changes espoused by Dr. Honeycutt and Dr. McClellan would actually create the kind of improvements to the process that the bipartisan group, the Keystone group identified as recommended changes to address directly address the concerns that you have just expressed.

Dr. McClellan, I want to ask you because you have served on advisory boards before, and so I am curious, did you have the occasion in your service to read all of the comments that were submitted in addition to the testimony that you heard when—during your service?

Dr. MCCLELLAN. As you have noted, I served on numerous committees. Committees that we are specifically focusing on here in terms of public input are those that come under the Clean Air Scientific Advisory Committee, which I chaired. I can assure you that I read every public comment that came forward. I am disappointed I cannot say that for many of my colleagues.

Ms. EDWARDS. But did you have——

Dr. MCCLELLAN. I also—

Ms. EDWARDS. Let me just—because I just have a limited amount of time. You served on those committees. You read all of the comments. Did you feel a need to respond to every single comment that was submitted to you even though you considered it in your service?

Dr. MCCLELLAN. There weren't many of those comments that deserved comment from the Agency as it proceeded with its rulemaking process.

Ms. EDWARDS. Dr. Grifo——

Dr. MCCLELLAN. It has done that in some cases. In many cases I think the Agency is deficient in responding. I think the Agency and the Committee frequently dismisses public comments to provide a three minute or a five minute comment period on very important matters is not sufficient. That is not engaging the public.

Ms. EDWARDS. So I am a little bit unclear. Dr. Grifo, I wonder if you can tell me in the work that you did coming up with—on these panels coming up with recommendations, do you believe that it is feasible given the level of work and the speed with which sometimes industry actually wants the stability and wants the Agency to operate that it would be possible with 17 full-time employees to respond to every single comment or even the significant ones? And is it your experience in reviewing these matters that there are times when comment is submitted and at a staff level it is reviewed and factors into the decision-making and the process

whether or not it is actually responded to or whether or not anyone was even listening during the hearings?

Dr. GRIFO. You know, in anticipation of today I did a little bit of a survey calling several colleagues that serve regularly on panels, as you do, sir. And in fact, you know, they do look at them. I mean they do read them. They do take them seriously. And, you know, if they don't appear in the final report is because the consensus of the Committee was that it wasn't appropriate for them to be in that final report.

So I think what is important here is that those public comments do come in and that there is an opportunity for the panel members to read them. But the written response could literally bring everything to a stop. Thousands and thousands and thousands of comments could be submitted on a weekly basis and there is no way there would ever be time to do anything else.

Ms. EDWARDS. Thank you. And then I want to ask you actually about the process a little bit and this idea of conflicts of interest because it is possible to have conflicts of interest that are fully disclosed or analyzed and still participate effectively in a process, isn't that true?

Dr. GRIFO. We currently have a system of waivers where waivers are actually given out so that people with conflicts may continue to serve. And one of the great things that came out of Dr. Holden's memo is this notion that all of those waivers should be made public.

Ms. EDWARDS. Thank you. And then lastly, let me just, you know, just say for the record. I mean there are plenty of times when a person has a conflict or some kind of interest and they have an expertise that is necessary, and it becomes necessary to involve them in the process and make sure that there is transparency in that disclosure and evaluation and move forward with the kind of assessments we need.

And with that, my time is expired.

Chairman STEWART. Thank you, Ms. Edwards.

So we now turn to Dr. Broun.

Mr. BROUN. Thank you, Mr. Chairman.

The Committee rules state that "Members of the Committee or Subcommittee have two weeks from the date of the hearing to submit additional questions in writing for the record to be answered by witnesses who have appeared in person. The letters of transmission and your responses thereto shall be printed in the hearing record." Dr. Grifo, you testified in front of the Subcommittee on Investigations and Oversight on October the 13th, 2011, for a hearing titled "The Endangered Species Act: Reviewing the Nexus of Science and Policy." November 16, 2011 you were sent questions for the record and asked for responses within two weeks. In fact, Mr. Chairman, I asked for a unanimous consent to enter into the record at this point the letter, as well as the questions sent to Dr. Grifo.

Chairman STEWART. Without objection.

[The information appears in Appendix II]

Mr. BROUN. Thank you. Despite multiple reminders from Committee staff, we still have not received your answers for a year-and-a-half. Why did you ignore the Committee's questions?

Dr. GRIFO. I sent them. I will look into why you don't have them.

Mr. BROUN. We have not received them and I am not sure that I can—well, if you say you sent them, I would like to have proof of that.

Dr. GRIFO. Absolutely.

Mr. BROUN. What date did you send those, Dr. Grifo?

Dr. GRIFO. I don't know. I would have to go back and look. I know they were late. It was not within the two weeks. I will clearly tell you that. But it was within a month, and I know I sent them. I will have to go back and look at the record.

Mr. BROUN. Well, we have not received those and I am not sure——

Dr. GRIFO. Well, then, we need to clear that up, sir.

Mr. BROUN. Okay. Well, why should this Committee believe that you would respond to Member's questions if the Committee staff has reminded you over and over again? And this is the first time I have heard as a Chairman of that Committee that you sent the answers. Why should we accept any thought that you will respond to the Committee's questions today?

Dr. GRIFO. Because I have testified dozens of times and I have Respondent on all of those occasions.

Mr. BROUN. Well, you have an even——

Dr. GRIFO. And I will have to look into this one and find out what happened, sir.

Mr. BROUN. Well, Dr. Grifo, you have—even in spite of the Committee staff asking you over and over again, this is the first time we have heard.

When you testified on October 13, you were under oath at that time and you indicated a willingness to respond to those questions. You say that you have. I think you failed to do so frankly. Why should we believe anything that you say?

Dr. GRIFO. Because I am telling you that you can look at the record for other hearings and you will see that I have responded, and I will look into this and see what happened.

Mr. BROUN. Well, I certainly hope so.

Dr. Honeycutt and Dr. McClellan, Dr. Grifo believes that the process of panelists recusing themselves from review proceedings if their work is being discussed. She believes that, that the panelists should recuse themselves. Do you believe this practice of self-recusal actually works, Dr. Honeycutt?

Dr. HONEYCUTT. No, sir. In fact, we have seen that not happen with the ozone case specifically—or especially. Actually, at the last CASAC public meeting, two study authors of the two studies that were the basis of the standard did recuse themselves at the last panel meeting, but previous panel meetings and they did not.

Mr. BROUN. Dr. McClellan?

Dr. MCCLELLAN. No, I would certainly agree that it has been inconsistent in the manner of which that has been done. Dr. Honeycutt is correct and I was in attendance at that last meeting. Those two authors did take special effort at that time. It was clear that there was some change underway in terms of the Agency.

Mr. BROUN. Do either of you have suggestions of how we should do the recusal process if a panelist's work is being discussed?

Dr. HONEYCUTT. Well, actually, in my opinion, they shouldn't have been on the panel in the first place.

Mr. BROUN. Okay.

Dr. HONEYCUTT. There were only two studies that were the basis of the standard and there are dozens of scientists that could have been chosen to be on the panel. And it makes no sense to me why you would have those study authors on the panel.

Mr. BROUN. So a better selection process.

Dr. McClellan?

Dr. MCCLELLAN. I would agree with Dr. Honeycutt statement there. In terms of that particular situation, there were a broad group of scientists that could have served and it was probably inappropriate because of the very clear and central role of those individuals. Unfortunately, the situation was one in which the individual who was serving as Chair of CASAC was one of the authors in question. So he was put into a very difficult position.

Mr. BROUN. Well, thank you, gentlemen. My time is about up and I just want to say that I know when I talk to constituents and Georgia about the scientific integrity of EPA, I see a tremendous disgust and disbelief in the scientific integrity of EPA.

Mr. Chairman, with that I will yield back.

Chairman STEWART. Sir, thank you, Dr. Broun.

Mr. Weber?

Mr. WEBER. Thank you, Mr. Chairman.

I am going to start with you, Dr. Grifo. I believe you stated—well, let me say a couple things first. I heard it said one time that all scientists are only convinced of one thing, and that is that every scientist before them was wrong. Excuse me. They can't always agree. In fact, to Vice Chairman Stewart's first question, is there a perceived problem with the EPA? I think 66–2/3 of you agree and 33–1/3 disagree, case in point.

Dr. Grifo, I think you stated that any panel member should be "Special Government Employees." Is that accurate?

Dr. GRIFO. For this particular Science Advisory Board, yes.

Mr. WEBER. Yes, ma'am. Do you contend that only Special Government Employees can be unbiased?

Dr. GRIFO. No, sir. I contend that only Special Government Employees have full examinations for conflict of interest.

Mr. WEBER. So what you are saying is that normal people, not that Special Government Employees aren't normal, and we could debate that, are not able to be unbiased. And I want to specifically hone in on industry here. Would you agree with the statement that most American entrepreneurs want a good clean environment for themselves, their families, their employees, indeed their customers? I mean after all, the longer a customer lives, the more products they can buy. That sounds kind of selfish, doesn't it? Do you agree, disagree with that?

Dr. GRIFO. I agree that. You know, I can only answer that in one way, as a mom. And I think that, you know, there are moms across this country that care deeply about the health and safety of their children.

Mr. WEBER. Well, and that is very commendable. I am not a mom but I am a dad and I got 3 kids and 4–1/2 grandkids. And do you have any grandchildren?

Dr. GRIFO. No. Do I look that old?

Mr. WEBER. I highly recommend them.

Dr. GRIFO. Good.

Mr. WEBER. Just as long as they are EPA-certified. I will say that they do have emissions when they are babies though and so you might want to take that into account.

Dr. GRIFO. Yes, sir.

Mr. WEBER. I own a business, and air-conditioning business, where we dealt with the EPA over Freon issues, and I can tell you as a father and a grandfather, industry has a vested interest in making sure that we have the best product, the best environment——

Dr. GRIFO. Um-hum.

Mr. WEBER. —and I think that for us to be able to weigh in on fracking and some of the other issues that seem to be of some concern, we need industry experts, those who have demonstrated by their lives, their time, their investment in terms of money, blood, sweat, and tears that they care about this country, they care about the environment. I have been to many chemical factories with a lot of my colleagues when I was in the state legislature and I would have to say that industry—because of that dirty word profit motive—doesn't want emissions, doesn't want accidents, doesn't want spells. They want to do it the safest, cleanest, best way because it is the most profitable. Would you object? I mean do you agree that we are horribly underrepresented by industry on this council, in the EPA on this panel?

Dr. GRIFO. Every Scientific Advisory Committee under FACA must submit a charter. In that charter they have to describe what the committee is going to be doing and what balance means for that committee. That is what is important is that, you know, the folks who were putting the folks—people on that panel actually look at that charter, follow that charter.

I believe somebody submitted for the record the General Service Administration's requirements for plans for a balance committee and how that works. I support all of that and——

Mr. WEBER. My time is running out here. I just want to make the point that I believe we are.

Dr. McClellan, how about you? And then we will go to Dr. Honeycutt.

Dr. MCCLELLAN. Yeah, I—let me put it in sharp focus for you. In preparation for this hearing I went to the EPA's website and the Science Advisory Board. I looked through the participants on that, and as best I could tally them up in terms of, you know, where they came from——

Mr. WEBER. Industry experience?

Dr. MCCLELLAN. I looked at these 110 members of the seven standing committees. Eighty-seven of those were from academic institutions. There was one individual from a company that makes products. I looked——

Mr. WEBER. And let's go on to Dr.——

Dr. MCCLELLAN. —at the chartered SAB, something close to 50 individuals. They were four to one——

Mr. WEBER. You are making my point. Let me run over to Dr. Honeycutt real quick. Thank you.

Dr. HONEYCUTT. Yes, sir, I agree with you.

Mr. WEBER. Yes, well, boy, he is short and to the point.

Well, unfortunately, not every EPA representative does us—we don't get the luxury of having a video or he has gone out and talked about crucifying industry like the former Regional 6 EPA Administrator did, so we are not always fortunate to have that kind of biased out there. So it does exist. And I appreciate your comments. My time is expired.

Mr. Vice Chairman, I yield back.

Chairman STEWART. Yes, Mr. Weber. Thank you.

The Chair now recognizes the former Chairman, Mr. Hall.

Mr. HALL. Mr. Chairman, I thank you, and I really thank you for holding this hearing and the manner in which you have conducted it and your statements. The draft legislation being discussed today is a bill I think partially based on a bill I had introduced last year too late to get out of rules, but EPA Science Advisory Board Reform Act. I certainly look forward to your leadership on this because it is imperative that EPA's regulatory science be judged by truly independent experts.

According to the EPA's Peer Review Handbook, the choice of peer review should be based primarily upon reviewers' expertise, knowledge, skills, and experience. And we have heard Dr. Grifo talked of that. And I want to ask her some questions in a minute. But according to EPA's Peer Review Handbook, choice of peer reviewers should be so based and should include specialists from multiple disciplines. Similarly, the National Academy of Sciences found that it may be important to have an industrial perspective because of the individual's particular knowledge and experience are often vital and you could say are testimony.

Dr.—let me see who I want to get to next. I may just go directly to Dr. Grifo. You understand that one of the roles of an advisory committee is, as you said, to provide consensus among various identified interests or stakeholders, your statement, right?

Dr. GRIFO. My statement was that——

Mr. HALL. Was that part of your statement?

Dr. GRIFO. That—if they are appointed as representatives but not necessarily for every advisory.

Mr. HALL. No, I didn't ask you that. I just asked you if your statement was it should be among various identified interests or stakeholders? Yes or no?

Dr. GRIFO. No.

Mr. HALL. Good. Then are you going to write and correct your statements before, as you have had to do probably many times?

Dr. GRIFO. What my statement said was that there are two ways that people can be appointed. One is as Special Government Employees, which comes with the government ethics rules, most of them. The other way they can be appointed is as a representative. I did not say whether one should be one or the other. What I did say——

Mr. HALL. All right. Let me stop you there. I think I have heard all I want to hear from you. Do you think there is merit in acknowledging or making public any dissenting or minority opinions much like a court hearing? Do you think that is important? Yes or no?

Dr. GRIFO. There are different kinds of——
Mr. HALL. A yes——
Dr. GRIFO. —advisory committees.
Mr. HALL. —give me a yes or a no.
Dr. GRIFO. I can't give you a yes or no. It is more complex than that.
Mr. HALL. I didn't think you really could. All that time that you were with the research roundtable, did you tell them about the court opinion that was given for aluminum against the EPA? Did you mention that to them? Now, you were there with them I think 18 months. You surely got around to discussing something like that. How important is a court hearing, a court ruling, not something the EPA or the President has directed or the Nazis trying to put on people? That is not what you want. We are looking for science from people that will give us true science. I don't find you doing that. I am glad my time is almost over.
Chairman STEWART. Thank you, Chairman Hall.
Some of us have expressed interest in follow-up questions with maybe a brief second round, and I think we would like to do that if we could.
I would like to begin then, and go back to an example that I alluded to, although only quickly in my opening statements, and that is it is an example of, I think, one of the concerns that we have in this. As one of the members of EPA's SAB panel tasked to reviewing the Agency's hydraulic fracturing study, Dr. Jerald Schnoor published an article entitled "Regulate, Baby, Regulate," which characterizes a relationship between government regulators and the oil and gas industry as "cozy and sometimes corrupt."
Now, I would like to turn this just a little bit and then get your reaction to it. What is the title of the book had been something like Drill, Baby, Drill and the quote that I described characterized the relationship between regulators and environmental groups as being cozy and corrupt? Do you think if someone had taken that, that they would have been allowed to continue to serve or, as he was, allowed to serve on subsequent boards in that industry? Do you think that would have happened? Dr. Honeycutt?
Dr. HONEYCUTT. I wouldn't think so.
Chairman STEWART. Yes?
Dr. MCCLELLAN. I think it is very unlikely. The original question, there is an element of the door tends to swing one direction there.
Chairman STEWART. Yes.
Dr. MCCLELLAN. That individual clearly never would have made it there. But they probably would not have made it there because they may have owned stock in the company. They may have been an independent driller.
Chairman STEWART. Yes.
Dr. MCCLELLAN. So it is—the point is well made.
Chairman STEWART. Probably not. And Dr. Grifo, I would be particularly interested in yours. I mean if someone had made the statements as I described them, you know, Drill, Baby, Drill, and they described that relationship between, you know, environmental groups and regulators, would you have been comfortable allowing that person to continue to serve on the boards?

Dr. GRIFO. It would have depended on the overall balance of the committee. You don't, you know, eliminated conflict of interest, balance, bias. If you have people who you believe can take part in an open conversation, you want them there and you want to balance that point of view. You don't want to eliminate.

Chairman STEWART. And I agree with you actually. And I think that is a great point that, you know, you can have people with perceived biases as long as they are balanced. Although I do think that you reach a threshold, and it may have been reached and some comment like that that would have excluded that opinion. I mean again if someone had said describe the relationship between regulators and environmental groups as cozy and corrupt, I think that perhaps is a threshold that even excepting bias or prejudices in the panel would have made so many people uncomfortable with a preconceived notion, I think it would have made many of us uncomfortable. And yet, the doctor continued to serve on subsequent boards.

And I think that is just an example of a problem that we hope to address in this revised legislation from the former Chairman that we are happy to carry over from, you know, the previous Congress.

Yes?

Dr. GRIFO. I just think that the pieces and hear that talk about making public the list ahead of time and allowing people to know who is going to be appointed are critical to looking at that balance issue. I think that is really important.

Chairman STEWART. Well, and I agree with you. And, you know, along with that and in a separate area is this—and you have addressed this, although I don't think we have addressed it as strongly as I would have liked to, and that was this idea that it is okay for some of these members to have direct financial ties through grants or other financial, you know, financial vehicles that the government uses, and yet we are so readily exclude those who have financial ties to the industry. And agreeing with you, Dr. Grifo, as long as they are revealed, as long as the ethics of this are clear. I think that we can clearly bring in more balance.

And Dr. McClellan, as you indicated in your previous answer to a question, you know, some 100 members on one panel and only one from the industry. And final point I will make and then I will yield time, the fracking industry is an industry, if we think IT as being an industry that is very dynamic and has great changes, it is nothing compared with the technological advances we are seeing and fracking. I mean these processes are changing every day, every week. And if you are not reaching out to these industry experts and asking for their input to these, if you are talking to someone who hasn't been in industry for a few months let alone a few years, then you are not getting the appropriate response from them because the technology has passed them by.

Thank you again for your time today. And I now yield to the Ranking Member, Ms. Bonamici.

Ms. BONAMICI. Thank you very much, Chairman Stewart.

I want to start by saying that witnesses here today are all professionals with years of experience and deserve to be treated as such regardless of whether we agree or disagree with their posi-

tions. So I just wanted to state that for the record and I hope that the other Members will respect that as well.

I want to clarify something that came up in Mr. Weber's question. Dr. Grifo, in your written testimony this is very clear, but I am concerned about the record. I want to make sure that it is clear for those just listening as well. When you talked about how everyone on one of the EPA's SABs should be a Special Government Employee, I am concerned that some people thought that that meant that it could only mean somebody who was employed by the government and not an industry person. But your written testimony makes clear that when a member of a committee is—that is created to provide independent advice is appointed as a Special Government Employee, that is a specific term that requires that they comply with the government ethics rules.

So I want to clarify that for the record and perhaps, Dr. Grifo, if you could explain a little bit about what that means to be a Special Government Employee to really make clear what the requirements are and clarify that it does include people from industry. If they are appointed as a Special Government Employee, that doesn't mean you exclude industry people.

Dr. GRIFO. Absolutely. To be—it is just a way of appointing people to government employee—to advisory committees. It is a term that refers to the number of days per year that they work and so on. It is just—it is a piece of the bureaucracy.

But I think the other thing that is important is that, you know, academia does not mean no experience with industry. I think our academic world and the corporate world are increasingly interdigitated, and so to put someone in this pile, or this pile, it becomes a little bit artificial because I think we cross those piles on a regular basis.

Ms. BONAMICI. Thank you very much, Dr. Grifo. And just again to clarify that Special Government Employee does include people from industry——

Dr. GRIFO. Absolutely.

Ms. BONAMICI. —it simply means that they need to comply with the government ethics rules, which I happen to think is a good thing.

Dr. GRIFO. Absolutely.

Ms. BONAMICI. So thank you all for your testimony.

And I think, Mr. Chairman, that we have certainly identified several areas where we agree, and I look forward to working with you and getting the input of the other Members and hope we can come up with some meaningful policy that improves the process.

Chairman STEWART. Yes, thank you, Ms. Bonamici.

And then we now turn once again to Dr. Broun.

Mr. BROUN. Thank you, Mr. Chairman. Dr. Grifo stated that the provisions requiring that the scientific and technical points of view represented by fairly balanced is unnecessary because it is already included in the Federal Advisory Committee Act. However, Dr. Honeycutt, Dr. McClellan, would you agree that it is important for the points of view represented on advisory panels such as the SAB be balanced? Yes or no?

Dr. HONEYCUTT. Yes.

Mr. BROUN. Dr. McClellan?

Dr. MCCLELLAN. Absolutely. And let me elaborate just a bit.

Mr. BROUN. I have got just a little bit of time and you like to talk a lot, so I just needed a yes or no right there. I appreciate it. If you can collaborate in your written response if you would.

Do you believe that EPA's current advisory panels such as the SAB or the Clean Air Science Advisory Committee are balanced in terms of the points of view represented, Dr. Honeycutt?

Dr. HONEYCUTT. No, sir.

Mr. BROUN. Dr. McClellan?

Dr. MCCLELLAN. No.

Mr. BROUN. Dr. Grifo?

Dr. GRIFO. It depends on the panel.

Mr. BROUN. I asked yes or no.

Dr. GRIFO. I can't answer it that way. I am sorry.

Mr. BROUN. Okay. Nine members of the 2011 CASAC panel to review PM2.5 has signed a public letter which expressed dissatisfaction with the current standard, as well as a strong opinion of what the standard should be. This means that 40 percent of the review panel is of the same opinion as to the advisory work that they are tasked with. Would you say this represents an adequate balance of opinion, Dr. Honeycutt?

Dr. HONEYCUTT. No, sir.

Mr. BROUN. McClellan?

Dr. MCCLELLAN. No, they fail to distinguish between the science and the policy they were advocating.

Mr. BROUN. Okay. Dr. Grifo?

Dr. GRIFO. No comment. I am not that familiar with that particular panel. I would have to look at it.

Mr. BROUN. Well, Dr. Grifo, the SAB's 2011 mercury panel is comprised of 17 academics, three state regulatory members, one from USGS and one private sector industry representative. You said that the panels should be balanced. Would you say that this is a fairly balanced panel?

Dr. GRIFO. We don't have the information that the folks putting that panel together had about the specific backgrounds and details of those individuals.

Mr. BROUN. Well, I am not asking about——

Dr. GRIFO. They made a determination——

Mr. BROUN. —their background. I just——

Dr. GRIFO. —that it was balanced. Again——

Mr. BROUN. —told you, Ms.——

Dr. GRIFO. —the label of academia, the label of industry, they are intermixed. People go back and forth between those realms. What is important is that you look at it, look at the charter for the committee and make sure that it is balanced. On that, sir, we can agree.

Mr. BROUN. Well, I think it should be balanced. If those academics are going to be promoting whatever their academic bias might be, three state regulatory members, one from USGS, and only one from the private sector, this is not balanced. And I think we can all agree we need balance, we need scientific integrity, and frankly, I don't see that.

Mr. Chairman, I yield back.

Chairman STEWART. Yes, thank you, Dr. Broun.

Well, with that we conclude our hearing today. I would like to thank once again the witnesses for your valuable testimony as well as to the Members for their questions.

The record will remain open for two weeks for additional comments and written questions from the Members. And we ask the witnesses to respond to these written questions in a timely fashion.

Well, again, with our gratitude, the witnesses are excused and this hearing is adjourned.

[Whereupon, at 11:21 a.m., the Subcommittee was adjourned.]

Appendix I

Answers to Post-Hearing Questions

ANSWERS TO POST-HEARING QUESTIONS

Responses by Dr. Michael Honeycutt

U.S. House of Representatives
Committee on Science, Space, and Technology
Subcommittee on Environment

Questions for the Record – Responses by Dr. Michael Honeycutt
April 19, 2013

Hearing Title: Improving EPA's Scientific Advisory Processes

1. **According to the EPA's Peer Review Handbook, "the choice of peer reviewers should be based primarily upon the reviewers' expertise, knowledge, skills, and experience, and should include specialists from multiple disciplines..." Do you believe this guidance has been followed in selecting peer review panels?**

   The CASAC is composed of knowledgeable individuals who are experts in their respective fields including epidemiology, toxicology, medicine, atmospheric chemistry and botany. However, there are other experts who are equally qualified, with knowledge, skills and experience who could also contribute to the panel. For example, on the recent Particulate Matter CASAC, there is a notable lack of state and tribal participation. State risk assessors and toxicologists bring, in addition to scientific expertise, knowledge of implementation challenges that are useful when making policy decisions. Risk assessment is one discipline that has been woefully lacking in CASAC panels.

   One issue that needs to be addressed is the lack of impartiality sometimes observed on these panels. The EPA Peer Review Handbook also indicates that individuals who have publically taken sides on a particular issue, in the form of editorials or opinion pieces for example, should be excluded. Indeed, it has been our experience that the CASAC membership and written advice to the Administrator often lacks balance in terms of points of view. For instance, although there may be alternative points of view expressed in individual comments, these concerns often are not reflected in the correspondence sent to the Administrator[1].

2. **In your testimony you noted that in recent years, the trend in CASAC has been toward the inclusion of more epidemiologists from academia at the expense of other areas of expertise and representation from states and industry. Can you provide us with some examples of this, and explain how the loss or exclusion of these points of view and expertise can negatively impact the peer review process?**

   Comparing the 2001-2006 CASAC panel for Particulate Matter (PM) to the 2008-2012 CASAC for PM, individuals with a background in toxicology decreased from 8 to 4.

[1] A member of the 2008-2012 CASAC Particulate Matter Review Panel noted that the assessment did not address the heterogeneity of effects, especially the negative C-R coefficients for some areas, and recommended that the following language be included: "the range of potential unintended secondary adverse consequences have not be evaluated in this document. Thus the recommendations herein may, or may not, improve overall public health." (EPA-CASAC-10-015) However, these concerns were not articulated to the Administrator in the letter from the Chair of the CASAC.

While there was one panelist with industry perspective in the 2001-2006 panel[2], there were none in 2008-2012 panel. However, there was an increase in panelists from academia from 16 to 20. There appears to have been no tribal perspective on these panels in recent years. On the chartered CASAC, there are currently no members with state or tribal perspectives[3]. Involving scientists from state and tribal governments is also important to the peer review process. State scientists understand issues relating to background levels of pollutants, regional air dispersion, and the realities of implementing a NAAQS, in addition to their scientific expertise.

Exclusion of various areas of expertise has serious effects on the peer review process. For instance, toxicologists bring important knowledge to the review process in the form of characterizing personal exposure and a thorough understanding of mechanisms of action when quantifying potential risk. It is not sufficient to show statistical association between a particular level of pollutant and a given health outcome. It is necessary to understand who has been exposed, to what, how much, and how often, and how that chemical affects the body at various doses in order to adequately characterize potential hazard. In recent years, the view among epidemiologists has been that small statistical associations (often with Relative Risks very close to 1.0[4]) are sufficient to drive policy decisions to lower a given NAAQS[5]. Having a panel where one point of view is outweighed by another can lead to policy decisions made in the absence of the most thorough understanding of the issue at hand.

3. **At the hearing you stated that the measures outlined in the bill are common sense solutions that would address the problems you had identified, and that they are already in use by other groups including the National Academies of Science. Can you explain how National Academies peer review policy and practice is different from that employed at the EPA, and how EPA might learn from their example?**

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[2] There is precedent for including industrial perspectives on advisory panels. In the 1994-1996 CASAC Particulate Matter review panel, the chair of the committee was from industry (Dr. George T. Wolff, General Motors, Environmental and Energy Staff).

[3] http://yosemite.epa.gov/sab/sabpeople.nsf/WebCommittees/CASAC
One member represents the eigbt northeastern states through a non-profit organization, accounting for approximately 14% (1 out of 7 members) - most states and tribes are not represented. Industry, Federal and Tribal Governments have 0% representation on the current panel.

[4] http://benchmarks.cancer.gov/2002/07/epidemiology-in-a-nutshell/ "Relative risks or odds ratios less than 2.0 are viewed with caution." WHO/IARC: Breslow and Day (1980). Statistical methods in cancer research. Vol. 1. The analysis of case control studies. IARC Sci. Publ. No. 32, Lyon, p. 36. "Relative risks of less than 2.0 may readily reflect some unperceived bias or confounding factor, those over 5.0 are unlikely to do so." WHO: Craun and Calderon. How to interpret Epidemiological Associations. "[A]n increased risk of less than 50% (RR=1.0-1.5)…is considered by many epidemiologists to be either a weak association or no association." In addition to such scientific guidance, legal precedence also indicates that relative risks below two should not be considered to support a hypothesized relationship. The Federal Judicial Center Reference Manual on Scientific Evidence Third Edition (2011) provides the following guidance: "The higher the relative risk, the stronger the association and the lower the chance that the effect is spurious…because epidemiology is sufficiently imprecise to accurately measure small increases in risk, in general, studies that find a relative risk less than 2.0 should not be sufficient for causation. The concern is not with specific causation but with general causation and the likelihood that an association less than 2.0 is noise rather than reflecting a true causal relationship."

[5] See various editorials written by 2008-2012 PM CASAC Chair Johathan Samet. Also, in a recent talk at the Society of Toxicology Annual Meeting in San Antonio, TX one panelist went so far as to say that in epidemiology today "…p-value [statistical significance] doesn't matter anymore."

The NAS policy on committee composition and balance and conflicts of interest states "Conclusions by fully competent committees can be undermined by allegations of conflict of interest or lack of balance and objectivity." Having study authors, grant recipients, and panelists who have taken public stands on relevant topics who are hand-picked by the Administrator gives the perception that the CASAC may not be truly independent. Furthermore, exclusion of certain sectors (e.g. tribal entities and industry) may lead to exclusion of panelists with highly relevant experience and expertise. While this exclusion (particularly of industry scientists) is presumably an effort to minimize perceived conflict of interest, the unintended consequence is a perceived lack of balance in the resulting panel.

The NAS policy goes on to state with regard to individuals with a particular perspective (e.g. state government, special interest, or industry) "...such individuals, through their particular knowledge and experience, are often vital to achieving an informed, comprehensive, and authoritative understanding and analysis of the specific problems and potential solutions to be considered by the committee." Indeed involving scientists from multiple sectors can contribute to the peer review process. For example, scientists from state governments possess relevant knowledge relating to background levels of pollutants, regional air dispersion, and the realities of implementing a NAAQS. Scientists from industrial backgrounds may have additional (perhaps unpublished) information and unique knowledge that can contribute to the committee's review.

With regard to objectivity, the NAS policy states that "...views stated or positions taken that are largely intellectually motivated or that arise from the close identification or association of an individual with a particular point of view or the positions or perspectives of a particular group." The policy goes on to say that some potential sources of bias may be so substantial that "...they preclude committee service (e.g. where one is totally committed to a particular point of view and unwilling, or reasonably perceived to be unwilling, to consider other perspectives or relevant evidence to the contrary)." The current appointment of panelists who have authored studies upon which EPA policy is based may fall into this category. Indeed, it has been our experience while attending the public meetings of the CASAC that many panelists are intensely resistant to alternative hypotheses regarding the epidemiological literature on certain NAAQS chemicals.

Often, the authors of key studies utilized in EPA policy documents make specific recommendations or point-of-view statements in their publications. For example, in the most recent publication of the Harvard Six Cities Study, Lepeule and colleagues state "These results suggest that further public policy efforts that reduce fine particulate matter air pollution are likely to have continuing public health benefits."[6] The former chair of the CASAC recently wrote "For particulate matter, a decision will be forthcoming by year's end with regard to recommended reductions in the 24-hour and annual NAAQS. If the administrator follows the CASAC's recommendations, the NAAQS will be set at

[6] Lepeule et al. Environ Health Perspect. 2012 Jul;120(7):965-70.

lower levels for both particulate matter and ozone."[7] These types of public statements blur the line between interpretation of scientific evidence and policy advice and indicate a lack of impartiality.

The NAS policy also indicates that the committee should not be subject to any actual management or control by a Federal agency or officer. The charge questions provided to the CASAC when reviewing each document narrow the focus of the peer review, resulting in a form of control over the panel by the agency.

Conflict of interest is defined in the NAS policy as any financial *or other interest* which conflicts with the service of the individual because it (1) could significantly impair the individual's objectivity or (2) could create an unfair competitive advantage for any person or organization. A number of difficult questions arise when considering this definition. For instance: (1) does receiving an EPA grant impair an individual's objectivity; (2) does a particular perspective (e.g., an academician publishing essentially the same finding over many years or serving as the chair of a professional society that espouses the same fixed position on a particular issue) impair the individual's objectivity; and (3) does the information gathered during the deliberative process give any particular individual or organization an unfair advantage with regard to obtaining EPA grant funding? In fact, the NAS includes research funding and other forms of research support as a type of financial interest that could fall under conflict of interest policies.

Finally, one of the provisions in the draft bill requires advisory boards to respond to comments submitted by the public. Requiring advisory boards to answer questions and address comments made during their public participation portion of the review is not unreasonable. This requirement would ensure that the panel not only listens to the public comments, but also considers them in a significant way. In fact, the EPA currently compiles a "response to comment" document as a part of the NAAQS review process.

4. **In your opinion, how effective have recusals been at allowing EPA's scientific advisory panels to address concerns about member panelists directly or indirectly reviewing their own work?**

It is true that recusal is a good first step. However, ideally authors whose work is included in a significant capacity in document under review would not be involved in the review of that document. The concern is that although the individual may recuse himself or herself from the direct discussion of their own work, they still contribute to decision-making that is based on this work. Also, when an individual devotes a significant proportion of their career to a particular line of research, they may be inadvertently biased in their approach to a specific issue. In contrast, and equally well-qualified researcher in a slightly different field may have adequate knowledge and expertise to critically evaluate the topic at hand with less innate bias.

The NAS policy states that if a panelist has a conflict of interest, but is appointed to serve on the committee, they must be excluded from all deliberations and decisions on

[7] Samet. N Engl J Med 2011; 365:198-201.

applications for which the individual has a conflict of interest. The question then arises, for what portion of the deliberations must the individual recuse him/herself? It is clearly improper for the author of a study to evaluate their own work, but is it appropriate for them to opine on the appropriateness of the approach used in their work as it applies generally to the field? Does their interpretation of their own work bias their perspective on the remainder of the available relevant scientific literature? It would certainly be simpler to exclude such individuals from participating on the committee, especially given the extremely large pool of qualified candidates.

Responses by Dr. Roger McClellan

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

Hearing Questions for the Record
The Honorable Chris Stewart

Improving EPA's Scientific Advisory Processes

Dr. Roger O. McClellan
Advisor, Toxicology and Human Health Risk Analysis

1. *According to the EPA's Peer Review Handbook, "the choice of peer reviewers should be based primarily upon the reviewers' expertise, knowledge, skills, and experience, and should include specialists from multiple disciplines..." Do you believe this guidance has been followed in selecting peer review panels?*

Yes, the U.S. EPA has followed the guidance in the EPA's Peer Review Handbook to select peer reviewers based on the reviewers' expertise, knowledge, skills and experience. However, in addition, the U.S. EPA, using a narrow interpretation of Federal Advisory Committee Act (FACA), routinely excludes from participation any individuals employed in private industry who may be remotely impacted by the Committee's deliberations. This narrow interpretation of FACA was used recently to exclude a number of individuals knowledgeable of hydraulic fracturing from the recently assembled Advisory Committee addressing this topic. This narrow approach results in the formation of advisory committees that may not have essential first-hand knowledge of the subject being reviewed.

It is my opinion, that the U.S. EPA should emphasize the selection of peer reviewers based on expertise, knowledge, skills, and expertise and not automatically exclude private sector employees and consultants. In my opinion, the issue of potential employer bias can be dealt with through a transparent process of public disclosure of employment status and potential conflicts of interest by all Committee or Panel members.

2. *The OMB Information Quality Bulletin requires that agencies should rotate membership and avoid repeated use of the same reviewer in order to "obtain fresh perspective and reinforce the reality...of independence." This is echoed in the EPA Peer Review*

Handbook as well. Would you say that the EPA does a good job of avoiding re-using the same reviewers? Can you cite any specific example, such as individual NAAQS panels, that seem to have a relatively high level of "regulars"?

In considering this question it is important to recognize that the EPA Clean Air Scientific Advisory Committee consists of seven members who are ostensibly appointed by the Administrator. However, when a CASAC Panel is assembled by the EPA Science Advisory Board (SAB) staff, it may include on the order of a dozen or so consultants in addition to the seven CASAC members. While the membership of CASAC is regularly rotated there is a tendency of the SAB to engage some consultants on a reoccurring basis. Moreover, one also finds individuals who have authored various portions of the Integrated Science Assessments (previously identified as Criteria Documents) showing up in later reviews as CASAC Panel Members. Other individuals who have authored key studies on a particular criteria pollutant may also be appointed as consultants to CASAC Panels or as CASAC members. Close scrutiny will reveal a small pool of individuals participating in multiple roles in the NAAQS setting process. This is of particular concern when CASAC, in my opinion, over-steps its bounds and offers not only comments on the science informing the setting of the NAAQS, but identifies a narrow range of pollutant concentrations for a NAAQS which it views as acceptable. Such actions move the CASAC from an advisory role to a standard setting role, which is the exclusive domain of the EPA Administrator.

These comments also apply broadly to the Science Advisory Board (SAB) whose members are ostensibly appointed by the EPA Administrator. However, the membership of specific committees may be bolstered by the appointment of consultants. A careful review of the membership of SAB Committees will show a heavy representation of individuals from certain academic institutions and specific State agencies. The membership of EPA Advisory Committees is certainly not representative of U.S. scientists.

3. *In your opinion, how effective have recusals been at allowing EPA scientific advisory panels to address concerns about member panelists directly or indirectly reviewing their own work?*

It is apparent over the past half dozen years that the EPA SAB staff has become increasingly concerned about CASAC Panel Members reviewing their own published work. This concern has been reflected in a few recent public "recusals." However, these have been relatively rare. However, while these 'recusals" provide an illusion that the playing field has been leveled, it is more of an appearance than a fact. The CASAC process would probably be more effective if it actually encouraged open discussion and debate of the strengths and weaknesses of the science irrespective of the authorship of specific papers. Very little of the CASAC Panel work is done in public view. Most of the discussion takes place off-line and is only manifest in the written draft comments of the CASAC Panel Members in response to EPA staff written questions. In the next phase of the process designated "writers" integrate the comments of several Panel members as input to the CASAC letter to the Administrator. The focus is on preparation of the letter to the Administrator, not on discussion of the science. In my opinion, adherence to process takes priority over true scientific debate.

In my opinion, a major step forward in the CASAC Panel Advisory process would be a requirement at the beginning of each specific NAAQS review for all CASAC Panel Members to declare they have checked "at the door" their personal ideological views as to their personal preference for the outcome for the process, i.e. leave the NAAQS at its present level, increase the stringency or decrease the stringency of the NAAQS. In the absence of such an approach, many of the CASAC Panel members will judge the success of the process only with regard to whether it justified EPA proposing a more stringent standard.

Responses by Dr. Francesca Grifo

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

Hearing Questions for the Record
The Honorable Chris Stewart

Improving EPA's Scientific Advisory Processes

Dr. Francesca T. Grifo

1. You stated in your testimony that "scientists are not immune to having their work and conclusions influenced by their financial prospects." While you seemed to single out industry funding in your testimony, would you agree that scientists can also be influenced by the source of their research funding? For example, would you agree that if a panelist is reliant upon EPA grants for his research, this might influence his ability to review EPA rules and regulations?

   I would agree that scientists are not immune to having their work and conclusions influenced by their financial prospects. I would agree that sources of research funding should be disclosed to those managing advisory panels so that it might be evaluated in the context of all the information available on a given panelist as they consider that candidate for possible conflicts of interest and bias.

2. You identified self-recusals as a solution to panelists reviewing their own work. Please identity instances in which CASAC or Advisory Council on Clean Air Act Compliance Analysis members have recused themselves.

   To my knowledge this information is not available to the public. I would guess that one would have to ask those agencies for that information. I have however served on National Science Foundation panels in which this kind of self-recusal was routine and effective.

Appendix II

Additional Material for the Record

LETTERS SENT TO THE COMMITTEE BY VARIOUS GROUPS AND INDIVIDUALS EXPRESSING THEIR CONCERNS ABOUT THE PROVISIONS IN THE BILL SUBMITTED BY REPRESENTATIVE SUZANNE BONAMICI

Natural Resources Defense Council * Environmental Defense Fund * Clean Water Action * Physicians for Social Responsibility * Earthjustice * League of Conservation Voters

April 10, 2013

The Honorable Lamar Smith
U.S. House of Representatives
2409 Rayburn House Office Building
Washington, DC 20515-4304

The Honorable Eddie Bernice Johnson
U.S. House of Representatives
2468 Rayburn House Office Building
Washington, DC 20515-4330

Dear Chairman Smith and Ranking Member Johnson:

We are writing to express our strong opposition to H.R. 1422, the "EPA Science Advisory Board Reform Act of 2013." The bill, which would amend the Environmental Research, Development, and Demonstration Authorization Act of 1978, would hinder the ability of the Environmental Protection Agency's Science Advisory Board (EPA SAB) to reach timely, independent, objective, credible conclusions that can form the basis of policy. Notwithstanding changes made to the bill relative to that introduced in the 112th Congress (H.R. 6564), H.R. 1422 would still significantly weaken and complicate the SAB review process, with no discernible benefit to EPA or the public.

Our most serious specific concerns with the bill are described below, in the order in which the provisions appear:

P. 2, line 23 to P.3 line4, creating Section 8(b)(2)(C) in the underlying Act, **promotes inclusion of panelists with financial conflicts, as long as they disclose their conflicts and obtain a waiver**

The bill shifts the current presumption against including people with financial conflicts on SAB panels. The bill appears to effectively mandate participation of scientists with financial conflicts, as long as the conflicts are disclosed, notwithstanding the reference to one portion of existing ethics law.

Policies and practices to identify and eliminate persons with financial conflicts, interests, and undue biases from independent scientific advisory committees have been implemented by all the federal agencies, the National Academy of Sciences, and international scientific bodies such as the International Agency for Research on Cancer of the World Health Organization. The bill's provisions are inconsistent with a set of nearly universally accepted scientific principles to eliminate or limit financial conflicts. Following these principles is the way agencies, the public, and Congress should ensure their scientific advice is credible and independent.

P. 3, lines 9-11, creating a Section 8(b)(2)(E) in the underlying Act, **Intentionally creates committees of non-experts**

This language will impede high-quality scientific review. If the SAB is to be made up of experts, their own work may be relevant to a question under review. That work will often be one of dozens if not hundreds of relevant studies. This language would result in committees of non-experts lacking first-hand in-depth technical knowledge of the topic under discussion.

P.4, lines 18-24 to P.5, lines 1-3, Section 2(b)(1) and 2(b)(2)(A), **Expands the scope of the SAB's work, and increases the burden**

This provision broadens the scope of the SAB's work to include risk or hazard assessments proposed by the agency, a dramatic and unnecessary expansion. The expansion would increase the burden on the SAB and slow the Board's ability to complete review of the criteria documents, regulations and other matters that are within the Board's current scope of work.

P. 6, lines 22-25 to P.7, lines 1-4, creating a Section 8(h)(4) in the underlying Act, **Ensures endless delay, burden and red tape under the guise of "transparency"**

This provision would give industry unlimited time to present its arguments to the SAB. Industry representatives already dominate proceedings because of their greater numbers and resources. In addition, the requirement for the SAB to respond in writing to "significant" public comments is vague (who defines what is "significant," and how?) and would tie down the SAB with needless and burdensome process. It also misconstrues the nature of both the SAB's role and the role of public comment in the SAB process. The role of the SAB is to provide its expert advice to the Agency. The role of the public comments during this phase is to provide informative input to the SAB as it deliberates, but the final product of the SAB deliberation is advice from the panel members, not an Agency proposal or decision that requires response to public comment. Members of the public, including stakeholders, have multiple opportunities to provide input directly to the Agency.

In short, H.R. 1422 would alter the nature of the SAB, which has been largely successful in providing the EPA expert review of key scientific and technical questions and would encourage industry conflicts in the review of scientific materials. It would also pile new and burdensome requirements on the Board, severely hampering its work and effectiveness. The result would be to further stall and undermine important public health, safety and environmental measures.

We urge you to abandon any efforts to advance this counter-productive bill. We would be happy to discuss our concerns with you further.

Sincerely,

Natural Resources Defense Council

Environmental Defense Fund

Clean Water Action

Physicians for Social Responsibility

Earthjustice

League of Conservation Voters

CONGRESSIONAL RESEARCH SERVICE MEMORANDUM ON EPA GRANTS TO MEMBERS OF SELECTED EPA ADVISORY COMMITTEES SUBMITTED BY REPRESENTATIVE DANA ROHRABACHER

Congressional Research Service

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.

THANK YOU LETTER AND QUESTIONS SENT TO DR. GRIFO FROM THE SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT HEARING ON OCTOBER 13, 2011, FOR THE HEARING TITLED, "THE ENDANGERED SPECIES ACT: REVIEWING THE NEXUS OF SCIENCE AND POLICY," SUBMITTED BY REPRESENTATIVE PAUL BOURN

RALPH M. HALL, TEXAS
CHAIRMAN

EDDIE BERNICE JOHNSON, TEXAS
RANKING MEMBER

U.S. HOUSE OF REPRESENTATIVES

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

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

November 16, 2011

Dr. Francesca Grifo
Senior Scientist and Director
Scientific Integrity Program
Union of Concerned Scientists
2 Brattle Square
Cambridge, MA 02138-3780

Dear Dr. Grifo:

On behalf of the Committee on Science, Space, and Technology, I want to express my appreciation for your participation in the October 13, 2011 hearing titled, *The Endangered Species Act: Reviewing the Nexus of Science and Policy.*

I have attached a verbatim transcript of the hearing for your review. The Committee's rule pertaining to the printing of transcripts is as follows:

> *The transcripts of those hearings conducted by the Committee and Subcommittees shall be published as a substantially verbatim account of remarks actually made during the proceedings, subject only to technical, grammatical, and typographical corrections authorized by the person making the remarks involved.*

Transcript edits, if any, should be submitted no later than November 30, 2011. If no edits are received by the above date, I will presume that you have no suggested edits to the transcript.

I am also enclosing questions submitted for the record by Members of the Committee. These are questions that the Members were unable to pursue during the time allotted at the hearing, but felt were important to address as part of the official record. **All of the enclosed questions must be responded to no later than November 30, 2011.**

All transcript edits and responses to the enclosed questions should be submitted to me and directed to the attention of John Serrano at John.Serrano@mail.house.gov. If you have any further questions or concerns, please contact Mr. Serrano at (202) 225-6371.

Thank you again for your testimony.

Sincerely,

Rep. Paul Broun, M.D.
Chairman
Subcommittee on Investigations
And Oversight

cc: Rep. Paul D. Tonko
Ranking Member
Subcommittee on Investigations
And Oversight

Enclosures: Transcript & Member Questions

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
HOUSE COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

Questions for the Record

"The Endangered Species Act: Reviewing the Nexus of Science and Policy"

Thursday, October 13, 2011
10:00 a.m. - 12:00 p.m.
2318 Rayburn House Office Building

Questions for Dr. Francesca T. Grifo,
Senior Scientist and Director, Scientific Integrity Program, Union of Concerned Scientists

Questions submitted by Dr. Paul Broun, Chairman

1. The USFWS recently settled two lawsuits that require the agency to make specific listing decisions regardless of what its own scientists feel are priority decisions. Do you support the lawsuits filed by the Center for Biological Diversity and the WildEarth Guardians?

2. Page two of your testimony cites public opinion polls supporting the Endangered Species Act as a reason for Congress to support the Act. Does this mean you also would support listing decisions based upon public opinion polls? Why or why not?

3. In light of fiscal constraints, how should the USFWS prioritize which species should be studied for listing under the ESA first? Should the timing of listing decisions be made based upon the earliest petition to be filed, what litigation is settled earliest, or on a priority system determined by the USFWS? Do you support increasing deficit spending to increase the number of USFWS employees to review these listing decisions?

4. In light of alleged agency misconduct by two federal employees described as "zealots" by a federal judge, how should such misconduct be treated?

5. Did any other entity besides UCS provide any assistance to you in preparing your written testimony for the Subcommittee's hearing? If so, please identify those entities and what support they provided?

6. When asked at the hearing to provide examples of "the most egregious examples of politicization of science," you mentioned that a former DOI employee "sent internal Department of Interior documents to various places." Have you or the Union of Concerned Scientists ever received internal agency documents that were, or might be considered, deliberative or pre-decisional? If so, please identify such documents, the names of the individuals that provided them, and attach a copy of the documents.

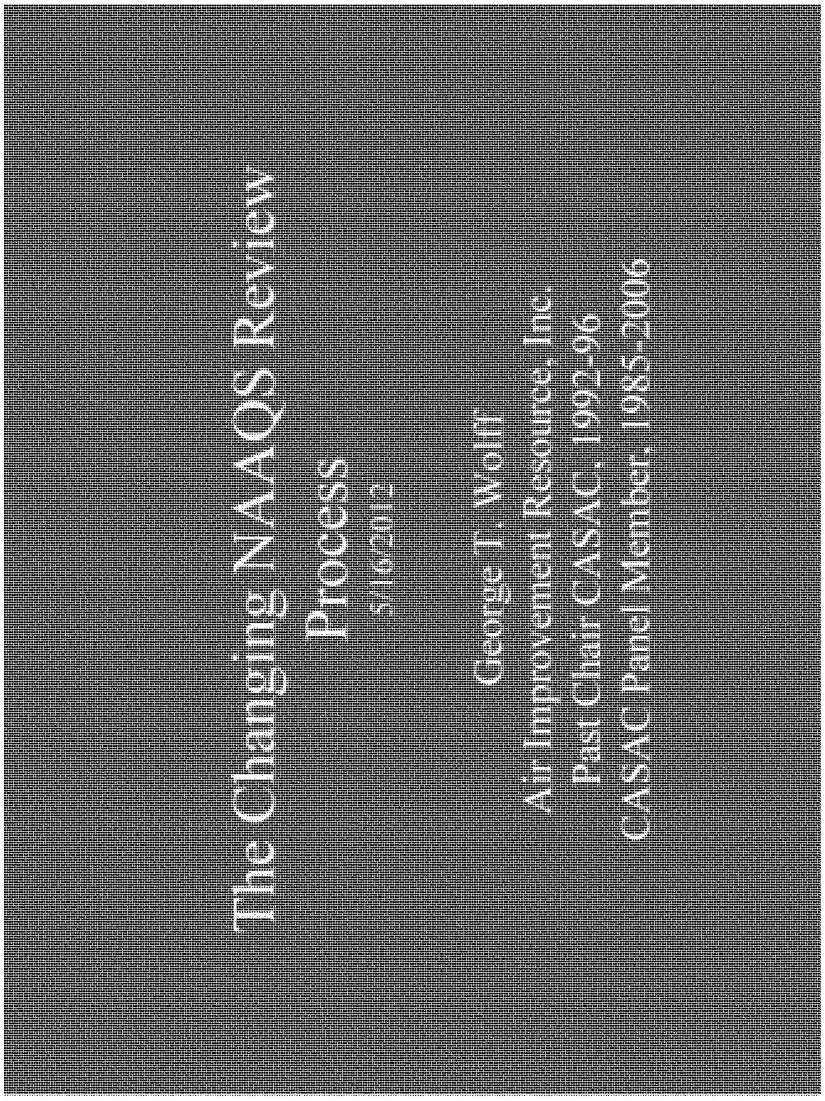
7. Please provide to the Committee the UCS's criteria for membership, as well as the total number of UCS members with scientific degrees, including the percentage of total membership that have scientific degrees.

8. Please provide a list of all lawsuits or petitions filed by UCS against the federal government in the last four years. Please provide the name of the lawsuit or petition, the subject matter of the filing, and the federal statute under which the lawsuits or petitions were filed.

9. Please provide the three most recent public IRS form 990s (including forms 990-PF, 990-N, and 990-EZ) filed by UCS and any other organization you represent.

10. Please provide a detailed accounting of both income received and expenses paid for lobbying activities for the last three years. Please list the issues and topics associated with that income or expense.

GEORGE T. WOLFF, THE CHANGING NAAQS REVIEW PROCESS, SUBMITTED BY DR. MICHAEL HONEYCUTT



CAA Mandates
• EPA must set National Ambient Air Quality Standards (NAAQS) for the ubiquitous criteria pollutants (ozone, particulate matter [PM], carbon monoxide, sulfur dioxide, nitrogen dioxide, lead)
• EPA must review the scientific basis of each NAAQS every 5 years
• The Clean Air Scientific Advisory Committee (CASAC) will oversee the reviews and report directly to EPA Administrator

CASAC
• 7 independent scientists who have outstanding reputations in air pollution science—appointed for two 2-year terms
– Medical Doctors and other Health Experts
– Atmospheric Scientists
– Ecologists, Plant Biologists
– Economists, Risk Analysts
• Additional Consultants for specific reviews
– Ozone Panel - 22 members
– PM Panel - 23 members

Documents in a NAAQS Review
• Integrated Science Assessment (ISA) — Comprehensive review of the state of the science
• Risk and Exposure Assessment (REA) — Estimates risk associated with alternative NAAQS
• Policy Assessment (PA) — Contains EPA's staff recommendations for the level and form of the NAAQS based on the science in the ISA

Steps in the NAAQS Review
1. CASAC provides reviews of ISA drafts to EPA
Administrator in an iterative process
2. CASAC provides reviews of REA and PA drafts to the
Administrator in an iterative process
3. EPA publishes proposal to maintain or revise NAAQS in
the Federal Register
4. 60-day public comment period
5. Final decision in Federal Register
Process typically takes 4–5 years

Major Changes Have Occurred in the Review Process

- Up to the 1990s, a mix of human exposure–toxicology and epidemiology studies drove the level and form of the NAAQS
- Since the late 1990s, epidemiology in the absence of supporting human exposure and toxicological evidence has driven the NAAQS lower and lower
- Up to 2000, CASAC had a more balanced perspective with scientists from academia and industry
- In the 2000s, CASAC became dominated by academic epidemiologists who are funded by EPA and are opining on their own research

How Epidemiologists Came to Rule the World - I

- In the 1990s PM Review, EPA embraced the work of a small group of researchers who showed a statistical relationship between mortality and PM levels even though human exposure and toxicology studies could not show that this was biologically plausible at such low concentrations
- These studies did not pass the accepted epidemiological criteria to even suggest cause and effect, so EPA wrote their own criteria that applies just to air pollution studies
- Because such statistical methods do not identify thresholds, dose-response functions showed mortality could be generated down to a PM concentration of zero!
- Even though single pollutant studies showed that such relationships could be found with any air pollutant, EPA dismissed them in the 1990s O_3, NO_2, and CO reviews as being biologically implausible

How Epidemiologists Came to Rule
the World - II

Waxman's 2001 GAO Report
• Identified many deficiencies in EPA methods of evaluating potential conflict-of-interest in their advisory boards
• This resulted in EPA making significant changes in how they select and who they select to be on their advisory boards
• For CASAC, anyone with any ties to industry was eliminated
• CASAC is now dominated by academia and a number are environmental activists

Inhofe's 2012 OIG Review of CASAC
• Began March 16, 2012 by EPA Office of Inspector General
• Objective: to determine whether EPA has managed the CASAC and ACCACA federal advisory committees in accordance with applicable laws, regulations, and guidance pertaining to appearances of impartiality, balance of committee viewpoints and perspectives, rotation of members, potential conflicts of interest, and peer review
* Advisory Council on Clean Air Compliance Analysis

Some of Inhofe's Concerns
• EPA has violated it's impartiality rules by selecting members (and the chair) who have publically taken sides for a lower NAAQS
• EPA has appointed authors (and the chair) of key studies to review their own work
• EPA has failed to ensure balance on CASAC
• EPA has failed to follow rotation rules as one PM Panel member has been there for almost 10 years
• EPA has repeatedly selected members (and the chair) who are benefiting from millions of $'s in EPA research grants

Conclusions

- Is the NAAQS process broken?
  - No, but CASAC has become ineffective as an unbiased science review body
- Can CASAC be fixed?
  - The IGO Review initiated by Senator Inhofe holds some promise

EPA EVALUALION REPORT SUBMITTED BY DR. MICHAEL HONEYCUTT

U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF INSPECTOR GENERAL

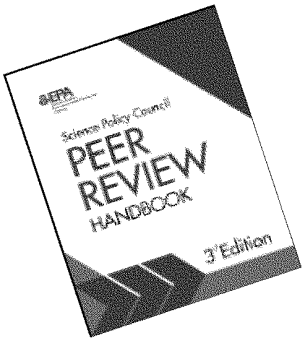
Catalyst for Improving the Environment

Evaluation Report

EPA Can Improve Its Process for Establishing Peer Review Panels

Report No. 09-P-0147

April 29, 2009



Report Contributors: Rick Beusse
Hilda Canes Garduño
James Hatfield
Geoffrey Pierce

Abbreviations

EPA	U.S. Environmental Protection Agency
FACA	Federal Advisory Committee Act
NAS	National Academy of Sciences
NCEA	National Center for Environmental Assessment
NIEHS	National Institute of Environmental Health Sciences
OIG	Office of Inspector General
OMB	Office of Management and Budget
ORISE	Oak Ridge Institute for Science and Education
SAB	Science Advisory Board
TERA	Toxicology Excellence for Risk Assessment

Cover photo: Cover of EPA's Peer Review Handbook, 3rd Edition, 2006 (EPA Number EPA/100/B-06/002). (EPA photo)

U.S. Environmental Protection Agency
Office of Inspector General

09-P-0147
April 29, 2009

At a Glance

Catalyst for Improving the Environment

Why We Did This Review

The Office of Inspector General (OIG) conducted this review in response to a request from the former U.S. Environmental Protection Agency (EPA) Deputy Administrator. We evaluated whether (1) current laws, regulations, guidance, and other relevant requirements for EPA expert peer review panels are adequate to produce objective scientific reviews, and (2) the current system of populating and managing such panels could be improved.

Background

Peer review is a process for enhancing a scientific or technical work product so that the decision or position taken by the Agency, based on that product, has a sound, credible basis. EPA's National Center for Environmental Assessment produces highly influential scientific assessments such as human health risk assessments; thus, it is one of EPA's primary users of peer review services.

For further information, contact our Office of Congressional, Public Affairs and Management at (202) 566-2391.

To view the full report, click on the following link: www.epa.gov/oig/reports/2009/20090429-09-P-0147.pdf

EPA Can Improve Its Process for Establishing Peer Review Panels

What We Found

The laws, regulations, guidance, and other relevant requirements governing EPA's peer review process are adequate to produce objective scientific reviews, but certain areas of EPA operating guidance can be better defined.

When we compared the EPA National Center for Environmental Assessment's (NCEA's) peer review panel selection process with the processes used by other major science-based organizations, we found that NCEA's process does not differ in many aspects from those other processes. However, NCEA's current system for populating and managing expert panels can be improved:

- Although NCEA strives to select "impartial" panelists, this concept is vaguely defined and not explained in any NCEA-specific operating guidance.
- NCEA does not have procedures for addressing conflicts of interest or potential biases that become known after a panel has completed deliberations.
- There was no clear documentation of authority and responsibility for making final determinations regarding panel selection or how potential conflicts of interest were resolved.

Following a prior OIG report, NCEA improved its peer review process by developing a questionnaire for EPA contractors to use in identifying potential conflicts of interests or biases of prospective panel members. Also, according to the NCEA Director, NCEA recently started to document its peer review process and is implementing a quality assurance checklist to ensure EPA contractors follow EPA's procedures.

What We Recommended

We recommended that the Assistant Administrator for Research and Development, which oversees NCEA, improve management controls by better defining the concept of "impartiality" and maintaining records of all management decisions pertaining to the selection of peer reviewers, particularly resolution of potential conflicts of interest. We also recommended that the Assistant Administrator develop guidance to address conflict of interest issues that arise after panel formulation and amend contracts for external peer review services to require that panelists re-certify their conflict of interest status prior to the panel convening. The Office of Research and Development agreed with our recommendations, and the Assistant Administrator's planned actions meet the intent of our recommendations. Additional information is needed regarding the timeframe for the Agency's implementation of one of our recommendations.

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

OFFICE OF
INSPECTOR GENERAL

April 29, 2009

MEMORANDUM

SUBJECT: EPA Can Improve Its Process for Establishing Peer Review Panels
Report No. 09-P-0147

FROM: Wade T. Najjum
Assistant Inspector General for Program Evaluation

TO: Lek G. Kadeli
Acting Assistant Administrator for Research and Development

This is our report on the subject evaluation conducted by the Office of Inspector General (OIG) of the U.S. Environmental Protection Agency (EPA). This report contains findings that describe the problems the OIG has identified and corrective actions the OIG recommends. This report represents the opinion of the OIG and does not necessarily represent the final EPA position. Final determinations on matters in this report will be made by EPA managers in accordance with established audit resolution procedures.

The estimated cost of this report – calculated by multiplying the project's staff days by the applicable daily full cost billing rates in effect at the time – is $272,110.

Action Required

In accordance with EPA Manual 2750, *EPA's Audit Management Process*, you should provide a written response within 90 calendar days. Your response should include a planned completion date for Recommendation 1. Since you submitted a corrective action plan that sufficiently addresses Recommendations 2 through 7, we are "closing" all recommendations, except for Recommendation 1, in our tracking system upon issuance of this report. These recommendations will be tracked to completion in the Agency's tracking system. No further response is required for Recommendations 2 through 7. As outlined in EPA Manual 2750, the Agency is responsible for tracking the implementation of these actions in its Management Audit Tracking System. We have no objections to the further release of this report to the public. This report will be available at http://www.epa.gov/oig.

If you or your staff have any questions regarding this report, please contact me at (202) 566-0827 or najjum.wade@epa.gov; or Rick Beusse, Director for Program Evaluation, Air and Research Issues, at (919) 541-5747 or beusse.rick@epa.gov.

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Appendices

Purpose

In response to concerns about the U.S. Environmental Protection Agency's (EPA's) handling of allegations of impartiality on one of its peer review panels, former EPA Deputy Administrator Marcus Peacock requested that the Office of Inspector General (OIG) review EPA's peer review process. The objectives of our review[1] were to determine whether:

- current laws, regulations, guidance, and other relevant requirements for such panels are adequate to produce objective scientific reviews; and
- the current system of populating and managing such expert panels could be improved.

Background

The foreword to EPA's Peer Review Handbook notes that strong, independent science is of paramount importance to EPA's environmental policies. The quality of the science that underlies EPA's regulations is vital to the credibility of EPA's decisions and, ultimately, the Agency's effectiveness in protecting human health and the environment. The peer review process enhances a scientific or technical work product so that the decision or position taken by the Agency, based on that product, has a sound, credible basis. It involves the review of a draft product by specialists in the field who were not involved in producing the draft. The peer reviewers then issue a report – an evaluation or critique – that is used by the authors of the draft to improve the product so that the final work product will reflect sound technical information and analyses. As described in the Handbook, peer reviewers typically evaluate the:

- clarity of hypotheses,
- validity of the research design,
- quality of data collection procedures,
- robustness of the methods employed,
- appropriateness of the methods for the hypotheses being tested,
- extent to which the conclusions follow from the analysis, and
- strengths and limitations of the overall product.

EPA's National Center for Environmental Assessment (NCEA), within EPA's Office of Research and Development, produces highly influential scientific assessments and thus is one of EPA's primary users of peer review services. EPA's NCEA uses extramural instruments, such as contracts and interagency agreements, to obtain peer review services to review highly influential scientific assessments, such as human health risk assessments. NCEA oversees the peer review process.

[1] The Deputy Administrator also asked OIG to determine whether the actions taken by EPA or the panelists were done consistent with existing federal law, regulations, guidance, and other relevant requirements. This objective was addressed in a separate OIG report.

Laws, Regulations, and Guidance Applicable to EPA Peer Reviews

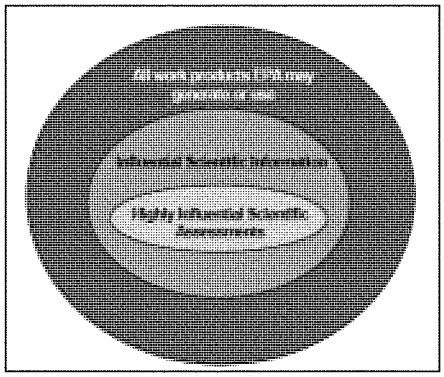
The primary laws, regulations, and guidance governing peer review at EPA include the Office of Management and Budget's (OMB's) "Final Information Quality Bulletin for Peer Review," EPA's Peer Review Handbook, and the Federal Advisory Committee Act (FACA).

OMB's Bulletin, issued in 2004, is the primary guidance for government agencies regarding peer reviews. The OMB Bulletin was based primarily on procedures used by the National Academy of Sciences (NAS). The OMB Bulletin established four key criteria to guide federal agencies in selecting a peer review panel.

1. Expertise is the most important factor when selecting a panelist.
2. Except for situations where it is unavoidable, panelists should be free of conflicts of interest. A "conflict of interest" is any financial or other interest that conflicts with the service of an individual on the review panel because it could impair the individual's objectivity or could create an unfair competitive advantage for a person or organization.
3. Panelists should be independent. The panelists should not have worked on the product being reviewed.
4. The panel should be balanced. Reviewers should be selected to represent a diversity of scientific perspectives.

EPA's January 2006 Peer Review Policy memo establishes the policy for peer review of scientific and technical work products, including economic and social science products that are intended to inform Agency decisions. EPA's Peer Review Handbook is the Agency's primary guidance governing peer reviews. The Handbook was most recently revised in 2006 to be consistent with the provisions of the 2004 OMB Bulletin. Although the Handbook outlines EPA's preferred approach to ensuring the quality of peer reviews conducted or initiated by the Agency, it is not a requirement.

Figure 1. Relation between all EPA work products and those considered influential scientific information or highly influential scientific assessments



Source: EPA Peer Review Handbook, 3rd Edition (2006)

The principle underlying EPA's Peer Review Policy is that all influential scientific and technical work products used in decision making will be peer reviewed. Determining whether a scientific and/or technical work product is "influential" or "highly influential" is done on a case-by-case basis, taking into account various criteria and the circumstances surrounding the use of the work product. OMB defines highly influential scientific assessments as influential scientific information that the Agency considers (1) could have a potential impact of more than $500 million in any year; or (2) is novel, controversial,

or precedent-setting, or has significant interagency interest. The OMB Bulletin calls for additional peer review procedures for highly influential scientific assessments.

The FACA governs committees that advise the federal government on a variety of issues, including peer review of scientific research. Among other requirements, FACA committee membership must be balanced in terms of points of view represented and the functions to be performed by the committee. EPA's Science Advisory Board (SAB) is a FACA committee and often conducts peer reviews of EPA products. Consequently, the SAB must manage its peer review panels in accordance with FACA requirements. Some statutes, such as the Clean Air Act, mandate a peer review process for certain EPA decisions. These peer reviews are conducted by FACA Committees supported by SAB, and are subject to FACA requirements.

NCEA's Peer Review Process

There are no laws or regulations specifying requirements for the peer reviews conducted by NCEA. The peer review mechanism used by NCEA to conduct peer review in any particular case is within its discretion. The majority of NCEA's peer reviews are for assessments conducted for the Integrated Risk Information System program. Integrated Risk Information System documents describe the health effects of individual substances and contain descriptive and quantitative information on their cancer and noncancer effects. The system is described in *EPA's Integrated Risk Information System: Assessment Development Procedures*. These procedures allow for OMB and interagency review and input on the external peer review charge questions developed by EPA. NCEA's process for peer review includes:

- conducting all peer reviews for influential scientific information, including highly influential scientific assessments and work products, by peer review panels in accordance with the Agency's Peer Review Handbook;
- providing members of each panel access to public comments received on the documents under review; and
- using the specified Conflicts of Interest questionnaire (the questionnaire includes a series of yes/no questions and request for supporting documentation) when peer review services are obtained through contracts and interagency agreements.

Specific requirements for conducting peer reviews are included in contract and interagency agreement statements of work. Depending upon the scientific product, NCEA may obtain peer review services from the NAS, the SAB, an EPA contract, or under an interagency agreement (at the time we conducted our review, NCEA had an interagency agreement with the Department of Energy's Oak Ridge Institute for Science and Education (ORISE)). According to NCEA officials, the assessments dealing with the most complex issues are given to the NAS to peer review; these occur about one every few years. Other assessments dealing with complex issues are given to SAB for peer review; these average from two to four each year. The majority of assessments are either reviewed under the peer review contract or an interagency agreement with another federal agency; in the past few years, NCEA has predominantly obtained peer review services for IRIS assessments through the ORISE interagency agreement. As of March 2009, NCEA does not plan to acquire peer review services under the ORISE interagency agreement since it expires in March 2009 and funds are no longer available to purchase such interagency services.

Noteworthy Achievements

In response to a prior OIG evaluation,[2] NCEA developed a questionnaire and received OMB approval for EPA contractors to use the questionnaire to help identify potential conflicts of interest or potential biases that may affect the selection of a potential panel member. The questionnaire asks potential panelists to address possible financial conflicts of interest of prospective panelists and their family members, as well as possible non-financial independence and impartiality issues.

During the current evaluation, NCEA started taking actions to improve its peer review process. According to the NCEA Director, NCEA is developing a description of the peer review process used in the Integrated Risk Information System program that it intends to post to its Website as a reference for staff and others.

Scope and Methodology

Our review was limited to a design evaluation of EPA's external peer review process, with a primary focus on NCEA's peer review process. Accordingly, our report contains recommendations that apply to EPA's external peer review process in general, as well as recommendations that apply specifically to NCEA's process. NCEA oversees the peer review of EPA's health risk assessments, specifically the peer review panel process that prompted the former EPA Deputy Administrator's request to us. We reviewed the applicable laws, regulations, policies, and guidance related to the establishment of peer review panels for the independent peer review of NCEA research. This review included OMB's 2004 bulletin, "Final Information Quality Bulletin for Peer Review"; and EPA's Peer Review Handbook, 3rd Edition, June 2006. We also reviewed the FACA, as amended in 1997. We interviewed key officials within NCEA to understand the process NCEA uses to establish peer review panels. We reviewed NCEA's peer review services contract and the interagency agreement used to acquire peer review support. We also interviewed individuals from the NAS, EPA's SAB, the Toxicology Excellence for Risk Assessment (TERA) organization,[3] and the National Institute of Environmental Health Sciences (NIEHS) to identify the practices used by other major organizations to identify and select peer review panelists.

We also reviewed our prior report on the peer review process (see footnote 2) and confirmed that NCEA implemented the recommendations in that report. In addition, we reviewed two prior U.S. Government Accountability Office reports on the SAB's peer review process.[4]

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[2] EPA OIG. *Review of Conflict of Interest Allegations Pertaining to the Peer Review of EPA's Draft Report, "Exposure and Human Health Evaluation of Airborne Pollution from the World Trade Center Disaster."* Report No. 2005-S-00003. November 4, 2004.

[3] TERA is a non-profit, 501(c)(3) corporation organized for scientific and educational purposes. TERA's mission is to protect public health by developing and communicating risk assessment information, sponsoring peer reviews and consultations, improving risk methods through research, and educating the public on risk assessment issues.

[4] *EPA's Science Advisory Board Panels: Improved Policies and Procedures Needed to Ensure Independence and Balance.* GAO-01-536. June 12, 2001; and *Federal Advisory Committees: Additional Guidance Could Help Agencies Better Ensure Independence and Balance.* GAO-04-328. April 16, 2004.

We performed our evaluation between May 2008 and February 2009 in accordance with generally accepted government auditing standards issued by the Comptroller General of the United States. Those standards require that we plan and perform the evaluation to obtain sufficient and appropriate evidence to provide a reasonable basis for our findings and conclusions based on our objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our evaluation objectives.

Results of Review

We found that the laws, regulations, guidance, and other relevant requirements governing EPA's peer review process are adequate to produce objective scientific reviews, but EPA can better define certain areas of its operating guidance. NCEA's peer review process is similar to the process of other major peer review organizations we reviewed. However, NCEA can improve its system for populating and managing expert panels by better documenting conflict of interest decisions, establishing guidance for handling conflict of interest issues that arise after the panel has completed its deliberations, and providing more consistency between contractor and other third party procedures for selecting panels.

Key Steps in NCEA's Process Used to Determine Potential Conflicts of Interest and Impartiality

EPA's contractors and ORISE require potential panelists to complete conflict of interest questionnaires that address financial conflicts of interest of panelists and their family members, as well as non-financial independence and impartiality issues. Panelists must certify that their answers are correct. The questions solicit "yes" or "no" responses. If a potential conflict of interest is indicated, the contractor or ORISE seeks additional information from the potential panelist. If the contractor or ORISE have difficulty making a determination regarding conflict of interest or lack of impartiality, the matter is brought to the attention of EPA. If conflict of interest is identified, the contractor must notify EPA's Project Officer, who in turn brings the issue to the attention of NCEA's Director or Associate Director for Health for resolution.

Prior to the panel convening, ORISE asks the selected panelists to confirm by return e-mail that there are no changes to their previous conflict of interest certification form. If their responses to any of the questions have changed, they must explain the changes to ORISE. ORISE changed this procedure beginning in June 2007. ORISE now sends a copy of the panelist's completed conflict of interest questionnaire back to the prospective peer reviewer so that they can review their original answers before confirming current status.

NCEA's Process is Similar to Other Peer Review Processes

We compared NCEA's peer review panel selection process with the process of four other science-based organizations.[5] We found that NCEA's process does not differ in many aspects from the processes used by these other major science-based organizations. Appendix A provides the details on our comparison.

[5] The four organizations are the NAS, EPA's SAB, TERA, and NIEHS.

One noteworthy difference between NCEA's process and other organizations is panel selection and public input. FACA panels for NAS and the National Academy of Public Administration are required to obtain public comment on proposed panelists. While this requirement does not apply to EPA SAB panels, the SAB has adopted this practice. Unlike the NAS and the SAB, NCEA's consultants do not obtain public input or comment on proposed panel members. In addition, FACA panels such as those convened by SAB and NAS attempt to achieve consensus among its panelists, and concerns about the impartiality of panel members can be mitigated by balancing the panel. Peer review panels established through NCEA's extramural instruments do not seek consensus. Thus, NCEA does not mitigate the inclusion of impartial panel members through panel balance, but instead chooses to leave potentially partial (or biased) panelists off the panel.

TERA was the only organization we contacted that provides the basis of its conflict of interest decisions to the public. TERA's peer review reports identify appearances of potential conflicts of interest that panelists may have and provide TERA's reasons for selecting these panelists. NIEHS uses peer reviews to evaluate studies completed for their National Toxicology Program. Rather than solely relying on completed questionnaires, NIEHS also conducts searches to identify possible impartialities or biases possessed by potential panel members.

NCEA Can Improve its Peer Review Process in Certain Areas

Although NCEA's external peer review process incorporates many of the procedures and controls used by other peer review organizations, certain areas of the process can be improved to provide more consistency and transparency to the process. These areas are described below.

- Although NCEA strives to select "impartial" panelists, this concept is vaguely defined by OMB and EPA guidance and is not explained in any NCEA-specific operating guidance. Neither the 2004 OMB Bulletin nor the EPA Handbook defines what constitutes "impartiality." According to the Handbook, in general potential panelists who had a predominant influence on an organization's position or have taken a public position or "taken sides" should be avoided.

- There was no clear documentation of authority and responsibility for making final determinations regarding panel selection or how potential conflicts of interest were resolved.

- NCEA can improve staff and the public's understanding of its external peer review process by fully describing the process and making that description available to EPA staff and the public. For example, TERA provides a description of its peer review process and its procedures for panel selection on the Internet. NCEA currently does not have a comprehensive description of its external peer review process, although the NCEA Director said one is being developed and will be made available on its public Website.

- NCEA does not have procedures for addressing conflicts of interest or potential biases, or allegations of such that become known or alleged after a panel has begun or completed its deliberations. NCEA does not have a policy or procedures regarding the circumstances under which a panelist's pay may be recouped or withheld when the panelist is dismissed or resigns before completion.

- Although NCEA's contractors conduct Internet searches to identify potential conflicts of interest and appearances of bias or partiality, ORISE – the current provider of peer review services under an interagency agreement – does not conduct Internet background searches. NCEA could improve its peer review process by establishing procedures for providers of peer review services to follow when conducting independent background searches on prospective panelists.

- NCEA's contractors do not use similar procedures for identifying any changes in selected panelists' conflict of interest status. One of EPA's two contractors told us it asks panelists at the first meeting of the panel if there have been any changes in their conflict of interest status. Any changes should be brought to the attention of EPA officials. However, the EPA program manager for the contract could not provide documentation that the panelists' answers were placed in the peer review record. According to the EPA program manager for the second contractor, it does not ask panelists if there have been changes in their conflict of interest status. After our inquiry, the program manager told us it plans to incorporate procedures to identify whether any changes in status have occurred between the time panelists complete their conflict of interest questionnaire and begin panel deliberations.

- NCEA can improve its oversight of peer reviews conducted by third parties to better ensure these peer reviews follow contractual guidelines. NCEA is working to develop an oversight tool to help ensure that significant steps in the peer review process are followed. Such a tool could also be useful in providing oversight of NCEA's peer review contracts and any future interagency agreements NCEA may use to obtain peer review services.

Conclusions

Certain areas of NCEA's current system for populating and managing expert panels can be improved. Although NCEA strives to select "impartial" panelists, this concept is vaguely defined and not explained in any NCEA-specific operating guidance. NCEA does not have procedures for addressing conflicts of interest or potential biases that become known after a panel has completed its deliberations. We also found that there was no clear documentation of authority and responsibility for making final determinations regarding panel selection or how potential conflicts of interest were resolved. We concluded that NCEA did not have adequate controls to establish accountability for suitability determinations and rationale for including or excluding each panelist.

Recommendations

We recommended that the Assistant Administrator for Research and Development:

1. Establish criteria, definitions, and/or example scenarios for the Peer Review Handbook term "appearance of a lack of impartiality," under which contractors and other external peer review services providers should operate.

2. Require and confirm that peer review records are maintained throughout the peer review process and that these records include any correspondence and decisions related to suitability, or potential conflicts of interest or biases of prospective panelists. In cases where panelists with potential conflicts or biases are accepted on the panel, the records should include a memorandum of decision explaining the suitability and rationale for including or excluding each panelist, which is signed off on by an EPA official.

3. Publish a description of the peer review process used in the Integrated Risk Information System program as a reference for staff and others. The process description should clearly define the roles and responsibilities of persons involved throughout the peer review process.

4. Establish procedures for addressing conflict of interest and lack of impartiality issues that arise after panel selection. These procedures should discuss under what circumstances peer review panelists' pay may be recouped or withheld.

5. Amend all extramural instruments to call for background Internet searches on potential panel members.

6. Modify NCEA's peer review contracts to require written recertification from panelists, before a peer review panel is convened, stating that their responses to the questionnaire have not changed. A copy of the questionnaire completed by the panelist should be included with the request for a written recertification. For both contracts and interagency agreements, EPA should require that reviewers self report any changes that may impact their conflict of interest status or lack of impartiality status at any point in the process. In cases where the Agency obtains the services of a reviewer through purchase orders not connected with contracts or interagency agreements, or without compensation, the terms should likewise require that reviewers self report changes that may impact their conflict of interest status or lack of impartiality status.

7. Develop an oversight tool to ensure that external peer review service providers follow all significant steps in the peer review process.

Agency Comments and OIG Evaluation

The Agency agreed with the report's conclusions and recommendations and proposed corrective actions that the Office of Research and Development plans to take in response to our recommendations. For six recommendations the planned corrective actions and planned timeframes for completion meet the intent of our recommendations. We are closing Recommendations 2 through 7 in our tracking system upon issuance of this report. These recommendations will be tracked to completion in the Agency's tracking system. The Agency's planned action in response to Recommendation 1 also meets the intent of our recommendation, but additional information is needed regarding the timeframe for the Agency's implementation of this recommendation. Accordingly, Recommendation 1 remains open pending our receipt of an estimated completion date for the Agency's proposed corrective action for this recommendation.

The Agency also provided several technical clarifications and comments to the report. We made changes to the final report based on these comments, as appropriate. The Agency's complete written response is in Appendix B.

Status of Recommendations and Potential Monetary Benefits

RECOMMENDATIONS						POTENTIAL MONETARY BENEFITS (in $000s)	
Rec. No.	Page No.	Subject	Status[1]	Action Official	Planned Completion Date	Claimed Amount	Agreed To Amount
1	7	Establish criteria, definitions, and/or example scenarios for the Peer Review Handbook term "appearance of a lack of impartiality," under which contractors and other external peer review services providers should operate.	O	Assistant Administrator for Research and Development			
2	8	Require and confirm that peer review records are maintained throughout the peer review process and that these records include any correspondence and decisions related to suitability, or potential conflicts of interest or biases of prospective panelists. In cases where panelists with potential conflicts or biases are accepted on the panel, the records should include a memorandum of decision explaining the suitability and rationale for including or excluding each panelist, which is signed off on by an EPA official.	C	Assistant Administrator for Research and Development	6/30/09		
3	8	Publish a description of the peer review process used in the Integrated Risk Information System program as a reference for staff and others. The process description should clearly define the roles and responsibilities of persons involved throughout the peer review process.	C	Assistant Administrator for Research and Development	6/30/09		
4	8	Establish procedures for addressing conflict of interest and lack of impartiality issues that arise after panel selection. These procedures should discuss under what circumstances peer review panelists' pay may be recouped or withheld.	C	Assistant Administrator for Research and Development	6/30/09		
5	8	Amend all extramural instruments to call for background Internet searches on potential panel members.	C	Assistant Administrator for Research and Development	6/30/09		
6	8	Modify NCEA's peer review contracts to require written recertification from panelists, before a peer review panel is convened, stating that their responses to the questionnaire have not changed. A copy of the questionnaire completed by the panelist should be included with the request for a written recertification. For both contracts and interagency agreements, EPA should require that reviewers self report any changes that may impact their conflict of interest status or lack of impartiality status at any point in the process. In cases where the Agency obtains the services of a reviewer through purchase orders not connected with contracts or interagency agreements, or without compensation, the terms should likewise require that reviewers self report changes that may impact their conflict of interest status or lack of impartiality status.	C	Assistant Administrator for Research and Development	6/30/09		

RECOMMENDATIONS						POTENTIAL MONETARY BENEFITS (in $000s)	
Rec. No.	Page No.	Subject	Status[1]	Action Official	Planned Completion Date	Claimed Amount	Agreed To Amount
7	8	Develop an oversight tool to ensure that external peer review service providers follow all significant steps in the peer review process.	C	Assistant Administrator for Research and Development	6/30/09		

[1] O = recommendation is open with agreed-to corrective actions pending;
C = recommendation is closed with all agreed-to actions completed;
U = recommendation is undecided with resolution efforts in progress

Appendix A

Peer Review Process Steps

Process Steps	NCEA Contracts	NCEA-ORISE	NAS	EPA SAB	TERA	NIEHS National Toxicology Program
Prospective panelists identified from database of experts.	Yes	Yes	Partially	Yes	Yes	Yes
Public is allowed the opportunity to recommend panel members.	No	No	Yes	Yes	Yes, if requested by sponsor	Yes
Prospective panelists complete detailed conflict of interest and an appearance of a lack of impartiality questionnaire.	Yes	Yes	Yes	Yes	Yes	Partial [a]
Prospective panelists provide information on past employment, research, etc.	Yes	Yes	Yes	Yes	Yes	Yes
Independent research conducted to identify potential panelist biases or conflicts.	Yes	No	Sometimes	Yes	Yes	Yes
Panelists are questioned about potential conflicts noted from the information provided.	Yes	Yes	Yes	Yes	Yes	Yes
Names of prospective panelists published and public comment requested prior to final panel selection.	No	No	Yes	Yes	No	No
Selected panelists verify no changes in conflict of interest status just prior to panel meeting.	Yes (verbal)	Yes (e-mail) [b]	Yes (verbal)	Yes (written)	Yes (verbal)	Yes (written)
Agency decisions on potential conflict of interest documented in Peer Review report.	No	No	No	No	Yes	No

Source: OIG-prepared table using information obtained from NCEA, NCEA contractors, ORISE, NAS, SAB, TERA, and NIEHS.

[a] Instead of relying solely on information provided by panelists, NIEHS conducts independent research to determine whether potential biases or conflicts exist. NIEHS does not use a checklist. Potential panelists provide curricula vitae that address the needed information.
[b] Procedure changed to require documented re-confirmation that no conflicts exist.

Appendix B

Agency Response to Draft Report

April 24, 2009

OFFICE OF
RESEARCH AND DEVELOPMENT

MEMORANDUM

SUBJECT: ORD Response to the Office of Inspector General Draft Evaluation Report: EPA Can Improve Its Process for Establishing Peer Review Panels, Assignment No. OPE-FY08-0007

FROM: Lek G. Kadeli */s/*
Acting Assistant Administrator

TO: Wade T. Najjum
Assistant Inspector General for Program Evaluation
Office of Inspector General

Attached please find: (1) A summary table of Office of Research and Development's (ORD) responses to the Inspector General's seven recommendations and (2) summary of comments on the Draft Evaluation Report regarding Peer Review. The comments represent collaboration across ORD because many of the draft report's recommendations could have impact to others in ORD. Any recommendations that go beyond ORD will be discussed with the Science Policy Council.

Thank you for providing the report and giving consideration to our response.

cc: Kevin Teichman
Peter Preuss
Fred Hauchman

ORD's Response to OIG Draft Report

"EPA Can Improve Its Process for Establishing Peer Review Panels"
Assignment No. OPE-FY08-0007

This document is comprised of three sections:

1. Table of ORD's Response to IG's seven recommendations
2. Recommendations for editing the Report regarding the scope
3. Specific comments by page number
4. General comments regarding the recommendations

1. Table of ORD's Response to IG Recommendations

Rec. No.	Subject	Lead Responsibility	ORD's Recommendation	Planned Completion Date
1	Establish criteria, definitions, and/or example scenarios for the Peer Review Handbook term "appearance of a lack of impartiality," under which contractors and other external peer review services providers should operate.	Office of Science Advisor	ORD agrees with this recommendation. The Office of the Science Advisor (OSA) will coordinate with the Science Policy Council (SPC) to consider any potential revisions to the Agency Peer Review Handbook regarding establishing criteria, definitions and/or example scenarios for the term "appearance of a lack of impartiality." ORD will provide OSA with scenarios for consideration.	TBD in consultation with the SPC
2	Require and confirm that peer review records are maintained throughout the peer review process and that these records include any correspondence and decisions related to suitability, or potential conflicts of interest or biases of prospective panelists. The records should include a Memorandum of Decision explaining the suitability and rationale for including or excluding each panelist, which is signed off on by an EPA official	ORD	ORD agrees with this recommendation. For non-FACA reviews, ORD will develop documentation to specify the addition of a memo to ORD peer review files confirming records are maintained, and the inclusion of all correspondence and records of discussion during the peer review panel selection process. ORD will develop a Standard Operating Practice (SOP) and perform periodic audits of peer review files to ensure this new requirement is being met.	June 30, 2009
3	Publish a description of the peer review process used in the Integrated Risk Information System program as a reference for staff and others. The process description should clearly define the roles and responsibilities of persons involved throughout the peer review process.	ORD	ORD agrees with this recommendation. ORD is currently re-writing the IRIS peer review SOP description. The final IRIS peer review process SOP will be posted to the IRIS website for use by EPA staff, contractors, and the public.	June 30, 2009

4	Establish procedures for addressing conflict of interest and lack of impartiality issues that arise after panel selection. These procedures should discuss under what circumstances peer review panelists' pay may be recouped or withheld.	ORD	ORD agrees with this recommendation. ORD will develop procedures and document them in the IRIS peer review SOP. ORD will consult with the Office of General Counsel (OGC).	June 30, 2009
5	Amend all extramural instruments to call for background Internet searches on potential panel members.	ORD	ORD agrees with this recommendation. Based on the EPA's Science Advisory Board protocol, ORD will add direction to conduct background Internet searches to all NCEA contract task orders. ORD will consult with OGC.	June 30, 2009
6	Modify NCEA's peer review contracts to require written recertification from panelists, before a peer review panel is convened, stating that their responses to the questionnaire have not changed. A copy of the questionnaire completed by the panelist should be included with the request for a written recertification. For both contracts and interagency agreements, EPA should require that reviewers self report any changes that may impact their conflict of interest status or lack of impartiality status at any point in the process.	ORD	ORD agrees with this recommendation. ORD will develop additional language for contract task orders requiring initial written certification at the time of empanelment, written (email) recertification about two weeks prior to the panel meeting at the beginning of panel meetings, and self reporting of any changes that may impact their conflict status or lack of impartiality status at any point in the process. ORD will consult with OGC.	June 30, 2009
7	Develop an oversight tool to ensure that external peer review service providers follow all significant steps in the peer review process.	ORD	ORD agrees with this recommendation. ORD will develop a QA checklist for contractors to use for all ORD peer reviews.	June 30, 2009

2. Recommendations for editing the Report regarding the scope

The scope of the Report is defined in the Purpose section on Page 1 ("... EPA Deputy Administrator Marcus Peacock requested that the Office of Inspector General (OIG) review EPA's peer review process.") and the Scope and Methodology section on Page 4 ("Our review was limited to a design evaluation of EPA's external peer review process, with a primary focus on NCEA's peer review process.") The Report provides recommendations for the ORD Assistant Administrator as the Action Official to address. Some of the recommendations are within the scope of NCEA to address in full (recommendation 3, 6) whereas others (recommendations 1, 2, 4, 5, 7), while actionable by NCEA, also affect ORD and EPA more broadly. **We recommend that for each instance where the report makes reference to "EPA" and to "NCEA" that the appropriate level of the organization be reviewed to confirm that the scope of the organization being referenced is consistent with the intended scope of the text and recommendations.** For example, the Results of Review section on pages 5-7 refers only to NCEA, yet the scope of many recommendations on pages 7-8 is not limited to NCEA.

3. Specific comments:

Page 1, Background: the text of the report indicates that NCEA uses grants to obtain peer review services. This is not correct. NCEA has used contracts and Interagency Agreements to obtain peer review services.

Page 3, last paragraph, last sentence – replace "In the future" with "As of March 2009," NCEA does not plan to acquire peer review services under the ORISE ...

Page 5, "Key steps...," reference is made to the Deputy Director for Health"; the correct reference here should be to the "Associate Director for Health." In addition, on the bottom of page 5 of the report, the statement is made that "FACA panels are required to obtain public comment on proposed panelists." This statement is factually incorrect. FACA does not require this, and neither does EPA. The SAB does obtain public comment on proposed panelists; however, this is not an agency-wide requirement, it is an SAB best practice.

Page 6, the last bullet at bottom of this page. It is correct that ORISE did not conduct internet searches and it is correct that our other contractors, ERG and Versar, have conducted Internet background searches. ERG often does internet searches to identify candidates but does not do an independent internet search after receiving the self reporting questionnaire. Versar also does internet searches, particularly for controversial reviews.

Page 7, last bullet before "Conclusions," it is stated that NCEA is working with ORISE to develop an oversight tool. The specific reference to ORISE should be deleted and be stated instead as "NCEA is working to develop an oversight too..." since the peer review work with ORISE is ending.

4. General comments:

a) With regard to specific recommendations, one in particular (#2) would benefit from further elaboration. It states that peer review records should "include a memorandum of decision explaining the suitability and rationale for including or excluding each panelist." Two examples are given below to illustrate why additional explanation by the OIG would be helpful:

- Lists of prospective panelists are often lengthy, and many worthy candidates may be excluded simply because they are unavailable. Would a memo of decision be required for this circumstance, or is the OIG referring to willful exclusion?
- Conversely, when an individual is included on a panel, current practices for justifying their selection (background searches and documentation of expertise, work history, stature or prominence in the field, etc.) are in our view sufficient to explain the rationale, so long as there are no conflicts of interest. Perhaps a memo of decision is necessary only in those cases where a panelist is selected despite some objection or perceived bias

b) Regarding recommendation #6, in cases where the Agency obtains the reviewer through purchase orders not connected with contracts or IAGs, or without compensation, the terms should likewise required that reviewers self report changes that may impact their conflict of interest status or lack of impartiality status.

c) Finally, we have reviewed and are in support of the comments submitted by the Office of the Science Advisor. The comments will be submitted by OSA.[6]

[6] OIG Note: The Office of Research and Development clarified that it had already incorporated the Office of the Science Advisor's comments into the above response.

Appendix C

Distribution

Office of the Administrator
Acting Assistant Administrator for Research and Development
Director, National Center for Environmental Assessment
Acting Science Advisor
Agency Follow-up Official (the CFO)
Agency Follow-up Coordinator
Acting General Counsel
Acting Associate Administrator for Congressional and Intergovernmental Relations
Acting Associate Administrator for Public Affairs
Audit Follow-up Coordinator, Office of Research and Development
Acting Inspector General

GSA FEDERAL ADVISORY COMMITTEE MEMBERSHIP BALANCE PLAN
SUBMITTED BY DR. MICHAEL HONEYCUTT

GSA

GSA Office of Governmentwide Policy
Office of Committee and Regulatory Management

Federal Advisory Committee Membership Balance Plan

GSA Committee Management Secretariat

Background:

The Federal Advisory Committee Act (FACA), as amended (5 U.S.C. App.) and the FACA Implementing Regulations (FACA Regulations) (41 CFR 101-6 and 102-3) provide the basis for and guidance concerning the management and operation of Federal advisory committees. Typically, groups subject to FACA require open, pre-announced meetings; public access to discussions, deliberations, records and documents; opportunity for the public to provide, at a minimum, written comments; fairly balanced membership; and the evaluation of conflicts of interest for certain members. In general, the provisions of FACA apply when the government establishes or utilizes (i.e., manages and controls) a group, made up of two or more individuals which includes at least one non-Federal employee, to provide collective advice and recommendations to a Federal official. There are also exceptions and best practices that allow managers to solicit advice outside of the FACA structure.

This document provides guidance to Federal agencies on how to prepare the Membership Balance Plan that is required for discretionary, and is strongly recommended for non-discretionary, Federal advisory committees. Please work with your department or agency Committee Management Officer to ensure that applicable internal requirements are followed.

This is a best practices guidance document prepared by the U.S. General Services Administration (GSA) Committee Management Secretariat, the statutory government entity responsible for FACA oversight. Please send comments to: CMS@GSA.GOV. Please cite the title of this guidance in any correspondence.

Introduction:

Section 5(b)(2) of the FACA requires "...the membership of the advisory committee to be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee." The corresponding FACA regulations reiterate this requirement at 41 CFR § 102-3.30(c), and, for discretionary committees being established, renewed, or reestablished, require agencies to provide a description of their plan to attain fairly balanced membership during the charter consultation process with GSA (41 CFR § 102-3.60(b)(3)). The document created through this process is the Membership Balance Plan. The regulations further clarify that (1) the purpose of the membership balance plan is to ensure "that, in the selection of members for the advisory committee, the agency will consider a cross-section of those directly affected, interested, and qualified, as appropriate to the nature and functions of the advisory committee;" and (2) "[a]dvisory committees requiring technical expertise should include persons with demonstrated professional or personal qualifications and experience relevant to the functions and tasks to be performed." (41 CFR § 102-3.60(b)(3)).

FACA mandates that Federal advisory committees be balanced in the points of view represented by the members, but leaves it to the discretion of each agency on how to do this. The FACA regulations

offer guidance in achieving a balanced Federal advisory committee membership, which include considering:

(i) The Federal advisory committee's mission;
(ii) The geographic, ethnic, social, economic, or scientific impact of the Federal advisory committee's recommendations;
(iii) The types of specific perspectives required, such as those of consumers, technical experts, the public at-large, academia, business, or other sectors;
(iv) The need to obtain divergent points of view on the issues before the Federal advisory committee; and
(v) The relevance of State, local, or tribal governments to the development of the Federal advisory committee's recommendations." (41 CFR § III of App. A to Subpart B)

FACA requires all Federal advisory committees to be balanced, regardless of whether they are discretionary (agency authority) or non-discretionary (statutory or Presidential) committees. Although the FACA regulations only address the Membership Balance Plan requirements for discretionary committees, GSA recommends that Executive departments and agencies apply these requirements to non-discretionary committees as well. This is a good practice and is consistent with Section 5(b)(2) of FACA which requires balanced advisory committees.

This guidance document is intended to provide a framework for prospective, analytical thinking regarding committee membership balance, and further agency FACA compliance. Agencies are encouraged to include additional information beyond what is suggested in this guidance document, as they deem appropriate.

Elements of the Membership Balance Plan:

The FACA Membership Balance Plan informs, and is consistent with, the federal advisory committee's charter, especially the section on advisory committee membership and designation. The plan is submitted as supporting documentation when an agency establishes a Federal advisory committee. The agency should update the plan whenever a Federal advisory committee is renewed or reestablished, and also when a Federal advisory committee's charter is amended. The plan is a stand-alone document that describes how the agency intends to achieve balance in terms of the points of view represented and the functions to be performed by the Federal advisory committee. Elements of a Membership Balance Plan include:

(1) Name. State the legal name of the Federal advisory committee.

(2) Authority. Identify the authority for establishing the Federal advisory committee (e.g., cite the statute, Executive Order, or note that the Federal advisory committee is established under agency authority).

(3) Mission/Function. Describe the mission/function of the Federal advisory committee.
(a) If the Federal advisory committee is discretionary, the mission/function will be a primary factor influencing the balance of the Federal advisory committee.

(b) If the Federal advisory committee is statutory or created by Executive Order, the composition of the Federal advisory committee may already be prescribed by the authorizing legislation (which may result in a pre-determined balance of the members).

(4) Points of View. Based on the purpose of the Federal advisory committee, this section:

(a) should describe the process that will be used to ensure the committee is balanced in terms of the points of view represented for the function(s) to be performed by the committee. This should include identifying the categories (e.g., individual expertise or represented interests) from which candidates will be considered;

(b) could identify an anticipated relative distribution of candidates across the categories; and

(c) should discuss how a determination was made to appoint any individuals as Special Government Employee (SGE) or Representative (Rep) members.

This analysis will affect the size of the Federal advisory committee, how it will be structured, and whether it is balanced. Although numerical parity is not required, too many or too few individuals representing one interest or area of expertise could result in the Federal advisory committee not being balanced in the viewpoints represented. If the Federal advisory committee is statutory or created by Executive Order, the exact number of members or a cap on the total number of members may be specified in the authorizing legislation.

This section should clearly state that membership balance is not static and may change, depending on the work of the committee.

(5) Other Balance Factors. List any other factors your agency identifies as important in achieving a balanced Federal advisory committee. These factors, which are not legally required, could include, the geographic location of candidates, importance of including regional, state, or local government expertise, consideration of the impact on local or specific communities, diversity in work sector (e.g., private industry, academia), etc.

(6) Candidate Identification Process. Summarize the process intended to be used to identify candidates for the Federal advisory committee, key resources expected to be tapped to identify candidates (e.g., recommendations from current and former Federal advisory committee members, publication of nomination notices, search of relevant professional associations, etc), and the key persons (by position, not name) who will evaluate Federal advisory committee balance (e.g., the Designated Federal Official, agency FACA attorney, agency head, etc). The summary should:

(a) describe how the process will result in consideration of a cross-section of those directly affected, interested, and qualified, and/or will identify individuals with demonstrated professional or personal qualifications and experience relevant to the functions and tasks to be performed (41 CFR § 102-3.60(b)(3));

(b) identify the key agency staff (again, by position, not name) involved in determining balance on the Federal advisory committee;
(c) briefly describe how Federal advisory committee vacancies, if any, will be handled by the agency (vacancies, and the length of time they remain unfilled, can impact the balance of the Federal advisory committee); and
(d) state the membership term limit of Federal advisory committee members, if applicable. Term limits result in turnover of membership and new perspectives, which affects the balance of a Federal advisory committee.

(7) Subcommittee Balance. Subcommittees subject to FACA should either state that the process for determining Federal advisory committee member balance on subcommittees is the same as the process for the parent Federal advisory committee, or describe how it is different.

(8) Other. Provide any additional information that supports the balance of the Federal advisory committee.

(9) Date Prepared/Updated. Insert the actual date the Membership Balance Plan was initially prepared, along with the date(s) the Plan is updated. This is not the date the charter consultation is held with GSA.

FACA WEB References:

The Federal Advisory Committee Act (FACA) – *http://www.gsa.gov/portal/content/100916*

Implementing Regulations (41 CFR 101-6 and 102-3) – *http://www.gsa.gov/portal/content/104034*

Committee Management Secretariat Website - *http://www.gsa.gov/portal/content/104514*

Finding FACA Information (www.eFACA.gov) or *http://www.gsa.gov/portal/category/101111*

The GSA FACA Database (www.FACA.gov) or *http://www.fido.gov/facadatabase/*

Committee Management Secretariat
Office of Committee and Regulatory Management
January 2011