FOSTERING QUALITY SCIENCE AT EPA: PERSPECTIVES ON COMMON SENSE REFORM (PART I AND PART II)

HEARING

BEFORE THE

SUBCOMMITTEE ON ENERGY AND ENVIRONMENT

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

HOUSE OF REPRESENTATIVES

ONE HUNDRED TWELFTH CONGRESS

FIRST & SECOND SESSION

WEDNESDAY, NOVEMBER 30, 2011
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February 3, 2012

FOSTERING QUALITY SCIENCE AT EPA: PERSPECTIVES ON COMMON SENSE REFORM (PART I)

WEDNESDAY, NOVEMBER 30, 2011

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

The Subcommittee met, pursuant to call, at 2:13 p.m., in Room 2318 of the Rayburn House Office Building, Hon. Andy Harris [Chairman of the Subcommittee] presiding.

Subcommittee on Energy & Environment Hearing

Fostering Quality Science at EPA: Perspectives on Common Sense Reform

Wednesday, November 30, 2011
2:00 p.m. to 4:00 p.m.
2318 Rayburn House Office Building

Witnesses

Ms. Susan Dudley, Director, Regulatory Studies Center, and Research Professor of Public Policy & Public Administration, George Washington University

Dr. Alan Moghissi, President, Institute for Regulatory Science

Dr. Kenneth Green, Resident Scholar, American Enterprise Institute

Dr. Gary Marchant, Professor of Law and Executive Director, Center for Law, Science & Innovation, Arizona State University

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

HEARING CHARTER

Fostering Quality Science at EPA: Perspectives on Common Sense Reform

Wednesday, November 30, 2011
2:00 p.m. to 4:00 p.m.
2318 Rayburn House Office Building

PURPOSE

On Wednesday, November 30, 2011, the Subcommittee on Energy and Environment of the Committee on Science, Space, and Technology will hold a hearing to provide external perspectives on the need to reauthorize and reform science, research and development activities at the Environmental Protection Agency (EPA); explore the intersection of Agency-supported science and its regulatory mission; and receive focused recommendations to raise the level, quality, usefulness, and objectivity of EPA science, including any necessary changes to the Environmental Research, Development and Demonstration Authorization Act.

WITNESSES

Ms. Susan Dudley, Director, Regulatory Studies Center, and Research Professor of Public Policy & Public Administration, The George Washington University

Dr. Alan Moghissi, President, Institute for Regulatory Science

Dr. Kenneth Green, Resident Scholar, American Enterprise Institute

Dr. Gary Marchant, Professor of Law and Executive Director, Center for Law, Science & Innovation, Arizona State University

BACKGROUND

The Environmental Research, Development, and Demonstration Authorization Act (ERDDA) authorizes research and scientific activities at the Environmental Protection Agency (EPA). Originally enacted in 1976, Congress subsequently passed annual authorizations through fiscal year 1981. In addition to establishing annual authorization levels, these statutes also directed EPA policy in a variety of areas, including establishing the Office of Research and Development (ORD)[1], requiring a 5-year environmental R&D plan, and creating EPA's Science Advisory Board (SAB).

[1] See Appendix 1 for EPA organizational structure.

Year	Act	Public Law Number
1976	ERDDA	94-475
1977	ERDDA of 1978	95-155
1978	ERDDA of 1979	95-477
1979	ERDDA of 1980	96-229
1980	ERDDA of 1981	96-569

Since 1981, there have been a number of bills introduced to reauthorize ERDDA that were not ultimately enacted into law.[2] As a result, explicit authorization of EPA's environmental R&D ended at the end of fiscal year 1981. This failure to comprehensively reauthorize EPA research, development, and demonstration programs and activities illustrates a broader trend among expired environmental statutes. The Congressional Research Service notes this trend, stating "Although Congress somewhat recently has renewed the authorization of appropriations for certain EPA programs and activities through targeted amendments to various statutes, a more comprehensive reauthorization of many of the statutes that EPA administers has not been enacted for a number of years."[3]

In addition to ERDDA, EPA also derives authority for R&D activities through other major environmental statutes. For example, under the Clean Air Act, the EPA Administrator must issue criteria that "accurately reflect the latest scientific knowledge useful in indicating the kind of extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air."[4] Through the Safe Drinking Water Act (SDWA), EPA sets standards based on "the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices."[5] Similarly, the Clean Water Act (CWA) requires EPA to publish water quality information "accurately reflecting the latest scientific knowledge."[6]

In many cases, these major regulatory statutes also authorize specific R&D programs and activities. For example, the Clear Air Act established a national research and development program for the prevention and control of air pollution including establishing technical advisory committees and research on air pollutant monitoring. The SDWA authorized the Administrator of EPA to conduct research and studies relating to the causes, diagnosis, treatment, control, and prevention of physical or mental diseases resulting directly or indirectly from contaminants in the water including improved methods to identify and measure contaminants in drinking water and improved methods to identify and measure the health effects of contaminants in drinking water. The CWA directed the Administrator to establish national programs for the prevention, reduction, and elimination of pollution and as part of such programs to work in cooperation with other State and Federal agencies to coordinate and accelerate research,

[2] HR 3115 (1982), HR 2804 (1982), S. 1205 (1982), S. 2577 (1983), HR 2899 (1984), S. 1292 (1984), HR 2319 (1985), S. 2702 (1985), S. 1144 (1986), HR 2355 (1987), HR 1523 (1987), HR 2153 (1989), HR 4873 (1990), HR 2404 (1991), S. 1655 (1991), HR 1994 (1993), S. 1545 (1993), HR 2405 (1995), HR 1814 (1995), HR 3322 (1996), HR 1276 (1997), HR 1742 (1999), HR 1743 (1999).
[3] Congressional Research Service, "Environmental Laws: Summaries of Major Statutes Administered by the Environmental Protection Agency," RL30798, August 11, 2011.
[4] 42 U.S.C. §7408 (a)(2) (2000).
[5] 42 U.S.C. §300g-1(b)(3)(A)(i).
[6] 33 U.S.C. §1314 (a)(1).

investigation, experiments, demonstrations and studies relating to the causes, effects, extent, prevention, reduction and elimination of pollution in the navigable waters of the U.S.

The science enterprise at EPA is spread across program offices and regions. ORD is organized into three national labs (comprised of 18 separate labs) and four national centers (which have 19 divisions).[7] In addition to 18 labs within ORD, there are 9 labs split among several program offices and each of the 10 regions has its own lab.[8] In FY2010, the appropriations level for EPA Science and Technology activities (S&T includes ORD and the other 19 labs) was $874.9 million. The appropriations level for FY2011 was $840.3 million. The FY2012 House Committee-passed appropriations level is $777.6 million and the FY2012 Senate Committee draft appropriations level is $809 million.

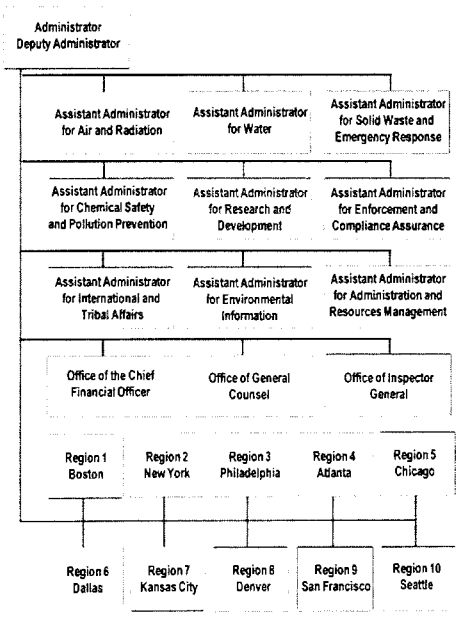
The fragmented nature of EPA R&D presents a challenge to program management and coordination, and has complicated efforts to evaluate the effectiveness of these activities. Numerous studies conducted by the EPA Office of Inspector General, the Government Accountability Office, and others have cited significant concerns with the science activities of the Agency and the difficulties in evaluating the usefulness of the science to program needs. These studies have offered recommendations on how to improve the science enterprise at EPA, but many of these recommendations have not been implemented.

[7] See Appendix 2.
[8] See Appendix 3.

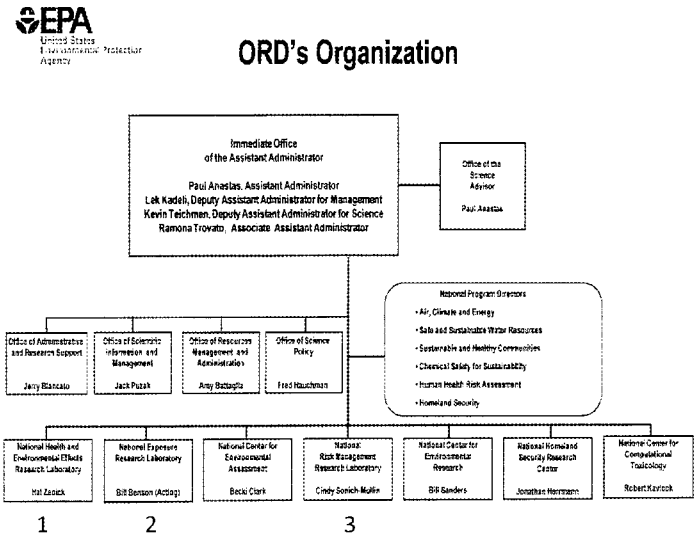
Appendix 1

EPA
United States
Environmental Protection
Agency

U.S. EPA Organizational Chart

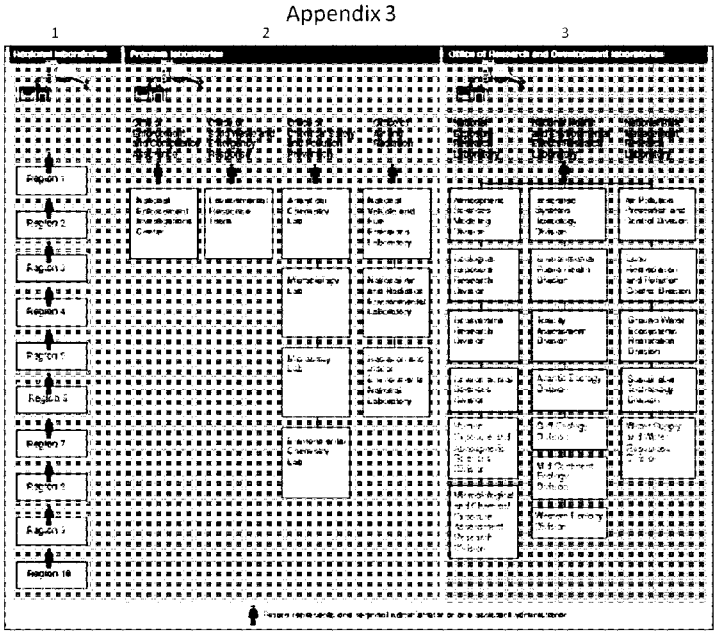


Appendix 2



The bottom of this chart shows three national labs and four national centers. The three national labs are broken down in Appendix 3.

Appendix 3



Column 1 shows 10 regional labs. Column 2 shows 9 program labs. Column 3 shows 18 ORD labs.

Chairman HARRIS. The Subcommittee on Energy and Environment will come to order. Good afternoon. Welcome to today's hearing entitled "Fostering Quality Science at EPA: Perspectives on Commonsense Reform." In front of you are packets containing the written testimony, biographies, and truth in testimony disclosures for today's witness panel.

I now recognize myself for five minutes for an opening statement.

I want to welcome everyone to this afternoon's hearing. This is the second in a series of hearings this Subcommittee will be conducting to provide ideas and guidance to reform science at EPA. Unfortunately, the Environmental Research, Development, and Demonstration Authorization Act or ERDDA, which is the statute authorizing R&D at EPA, as well as the Science Advisory Board, was last reauthorized for fiscal year 1981. Thirty years of Congressional neglect and the aggressive and unjustified regulatory train wreck being pursued by this Administration make the time right to evaluate reforms to environmental science at the agency.

Many things have changed since 1981 that demand renewed Congressional attention. Funds appropriated to EPA science and technology account have more than tripled from 1981 to 2010, and the agency's overall budget has ballooned to almost $9 billion. The agency now employs almost 18,000 people and maintains nearly 40 laboratories.

According to the Office of Management and Budget the overall effect of all major federal regulations in 1981, were a net cost savings of $1 billion. In contrast, in 2010, EPA's major rules alone represented over 23 billion in costs, a figure itself that many believe is a significant underestimate, and there have been disagreements as to the real benefits of these regulations.

There are also very pragmatic reasons for us to be keenly interested in reforming and reauthorizing science activities at the EPA. Given the dire fiscal straits that our country is facing, programs, activities, and agencies that are operating under expired or outdated authorizations will have targets on their backs as we seek to get our budgetary house in order.

In light of this the right reforms to EPA R&D programs will not only improve trust in the science that informs regulatory decisions but will also provide a framework to prioritize the most important functions and reduce unnecessary and wasteful spending elsewhere.

For instance, despite 1.2 million examples of successful hydraulically-fractured wells, the agency is moving forward with an unnecessary study in the area.

Some basic questions need to be asked. What should the role of EPA be in conducting research? Should it be limited to fundamental research? Should R&D be limited to supporting the agency's regulatory agenda? What is the relationship between EPA's science and policymaking missions? And how do we prevent the politicizing of scientific activities? How can Congress best ensure regulatory science that is reliable, peer-reviewed, transparent, understandable, and objective? Are structural changes necessary to improve the quality and independence of the agency's scientific advisory bodies? And do we have our environmental priorities right? And are we getting the most environmental bang for our buck?

This hearing follows up on testimony received two weeks ago from officials at the EPA's Office of Research and Development, Office of the Inspector General, and the Government Accountability Office.

Furthermore, in order to build a substantive record this is actually the ninth hearing on science and process at the EPA that this Committee has held so far in the 112th Congress. The Committee has also sent a series of letters to EPA and the Administration requesting further information about policies on transparency, cost benefit analysis, and peer review. Unfortunately, we are still waiting for responses to four letters sent since September.

Reforming environmental science should not be a partisan issue, as the 2009 report by the Bipartisan Policy Center's Science for Policy Project co-chaired by the former chair of the full Science Committee, Sherry Boehlert, explained, "A tendency to frame regulatory issues as debates solely about science, regardless of the actual subject in dispute, is at the root of the stalemate and acrimony all too present in the regulatory system today."

The report went on to recommend that Congress should include their recommendations, "In legislation as relevant programs are reauthorized," including suggesting the studies used in developing regulations should be subject to data access requirements, agencies and advisory bodies should be transparent in their approach to evaluating weighing studies, and that agencies should explicitly differentiate between scientific judgments and policy judgments.

These are reasonable core principles that I hope both sides can agree upon and which will advance fulfillment of the President's executive order requiring that, "Our regulatory system must be based on the best available science."

The diverse set of witnesses with us today will offer their views on these and other EPA scientific reform ideas and offer recommendations for improving and clarifying environmental R&D priorities. I hope these suggestions will highlight some potential avenues for bipartisan cooperation as our Subcommittee continues its work on these issues.

Again, I want to thank all the witnesses for appearing before the Subcommittee, and I look forward to a constructive discussion.

[The prepared statement of Mr. Harris follows:]

PREPARED STATEMENT OF CHAIRMAN ANDY HARRIS

I want to welcome everyone to this afternoon's hearing on Fostering Quality Science at EPA: Perspectives on Common Sense Reform.

This is the second in a series of hearings this Subcommittee will be conducting to provide ideas and guidance to reform science at EPA. Unfortunately, the Environmental Research, Development and Demonstration Authorization Act, or ERDDAA (ERDDA), which is the statute authorizing R&D at EPA as well as the Science Advisory Board, was last reauthorized for fiscal year 1981. Thirty years of Congressional neglect and the aggressive and unjustified regulatory train wreck being pursued by this administration make the time ripe to evaluate reforms to environmental science at the Agency.

Many things have changed since 1981 that demand renewed Congressional attention. Funds appropriated to EPA's science and technology account have more than tripled from 1981 to 2010, and the Agency's overall budget has ballooned to almost $9 billion dollars. The Agency now employs almost 18,000 people, and maintains nearly 40 laboratories. According to the Office of Management and Budget, the overall effect of all major federal regulations in 1981 was a net cost savings of $1 billion. In contrast, in 2010, EPA's major rules alone represented over $23 billion in costs—

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There are also very pragmatic reasons for us to be keenly interested in reforming and reauthorizing science activities at the EPA. Given the dire fiscal straits that our country is facing, programs, activities, and agencies that are operating under expired or outdated authorizations will have targets on their backs as we seek to get our budgetary house in order. In light of this, the right reforms to EPA R&D programs will not only improve trust in the science that informs regulatory decisions, it will also provide a framework to prioritize the most important functions and reduce unnecessary and wasteful spending elsewhere. For instance, despite 1.2 million examples of successful hydraulically-fractured wells, the Agency is moving forward with an unnecessary study in this area.

Some basic questions need to be asked: What should be the role of EPA in conducting research? Should it be limited to fundamental research? Should R&D be limited to supporting the Agency's regulatory agenda? What is the relationship between EPA's science and policymaking mission, and how do we prevent the politicizing of scientific activities? How can Congress best ensure regulatory science that is reliable, peer reviewed, transparent, understandable, and objective? Are structural changes necessary to improve the quality and independence of the Agency's scientific advisory bodies? And do we have our environmental priorities right, and are we getting the most environmental bang-for-our-buck?

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The diverse set of witnesses with us today will offer their views on these and other EPA scientific reform ideas, and offer recommendations for improving and clarifying environmental R&D priorities. I hope these suggestions will highlight some potential avenues for bipartisan cooperation as our Subcommittee continues its work on these issues.

I want to thank the witnesses for appearing before the Subcommittee and I look forward to a constructive discussion.

Chairman HARRIS. The chair now recognizes Mr. Miller, the Ranking Member, for five minutes for an opening statement.

Mr. MILLER. Thank you, Mr. Chairman. I appreciate your accommodating me by beginning slightly early this afternoon to allow me to cast votes in the Financial Services Committee, and I would also like to make this Committee's efforts in rewriting the authorization statute to be a bipartisan effort. I appreciate your willingness to work with us to try to make future hearings more useful to the Committee in informing that important work.

Today the Subcommittee meets again for part two of the EPA research and science, series of hearings. The first hearing two weeks ago was disappointing and a missed opportunity. The stated purpose of the hearing a couple weeks ago was to examine the ability

of EPA's research enterprise to meet the agency's mission to protect public health and the environment.

However, many of my colleagues decided instead to use their time to focus on EPA's hydraulic fracturing study rather than on that stated purpose. I believe the goal of this series of hearings should be to establish a useful Committee record to prepare the right legislation to reauthorize the Environmental Research, Development, and Demonstration Authorization Act, ERDDA.

Today's hearing does not appear to be any more likely to inform the Committee about structural and substantive concerns of stakeholders related to EPA's research activities, and it is not a balanced, comprehensive, or even a helpful hearing. This hearing looks like what we are seeing on the House Floor this week, a platform for anti-regulation, anti-science talking points, and as I said a couple of weeks ago, I hope that my Republican counterparts are truly interested in reform that will lead to better research to enhance public health and protect the environment.

Although we all agree that there are legitimate concerns related to EPA's research enterprise, this hearing doesn't really help us understand or address those issues. The agency's scientific research is important as more complex environmental issues emerge and evolve that need to be understood and addressed. Scientific research knowledge and technical information are fundamental to EPA's mission and inform its standard setting, regulatory compliance, and enforcement functions. That is why Congress saw fit to create advisory bodies at EPA like the Clean Air Scientific Advisory Committee, which was created to provide independent advice on the science and allow the Administrator to make regulatory decisions.

I really hope today that we would have a productive conversation about how best to position EPA to perform that mission, protecting human health and the environment. And if we are really serious about working towards reauthorizing ERDDA, which does need to be done as the Chairman said, after 30 years perhaps it is wise to revisit that statute, we must establish a Committee record that will offer us a wide range of views on how best to draft legislation that would serve the agency better, as well as the people that we all represent.

If that is the case, I hope that we can commit to working together after today to put together hearings and panels that will serve that purpose.

And with that, Chairman Harris, I yield back.

[The prepared statement of Mr. Miller follows:]

PREPARED STATEMENT OF RANKING MEMBER BRAD MILLER

Thank you Chairman Harris. Today the Subcommittee meets again for part two of the EPA research and science series of hearings. The first hearing two weeks ago was pretty disappointing and a missed opportunity. The stated purpose of our hearing a couple of weeks ago was to examine the ability of EPA's research enterprise to meet the agency's mission to protect public health and the environment. However many of my colleagues on the other side of the aisle decided to use their time to focus on EPA's hydraulic fracturing study rather than on that stated purpose. I believe the goal of this series of hearings is to establish a useful Committee record in preparation of writing legislation to reauthorize the Environmental Research, Development, and Demonstration Authorization Act (ERDDA).

Today's hearing does not appear to be any more likely to inform the Committee about structural and substantive concerns of stakeholders related to EPA's research activities. It is not balanced, comprehensive, or even helpful. This hearing looks just like what we are seeing on the House floor this week—the anti-regulation, anti-science talking points of the far right. As I said a couple of weeks ago, I hoped that my Republican counterparts were really interested in reform that will lead to better research to enhance public health and protect the environment. Although we all agree that there are legitimate concerns related to EPA's research enterprise, this hearing doesn't come close to helping us understand or address these issues. The agency's scientific research is important as more complex environmental issues emerge and evolve that need to be understood and addressed. Scientific research, knowledge, and technical information are fundamental to EPA's mission and inform its standard-setting, regulatory, compliance, and enforcement functions. That is why Congress saw fit to create advisory bodies at EPA, such as the Clean Air Scientific Advisory Committee (CASAC), which was created to provide independent advice on the science which allows the Administrator to make regulatory decisions.

I really hoped that today we would have a productive conversation about how best to position the EPA to perform its mission of protecting human health and the environment. If we are really serious about working towards reauthorizing ERDDA, we must establish a Committee record that will offer us a wide-range of views on how best to draft legislation to better serve the agency as well as the people that we all represent. If that is the case, I hope that we can commit to working together after today in formulating hearings and panels that will serve that purpose.

With that, Chairman Harris, I yield back.

Chairman HARRIS. Thank you very much, Mr. Miller.

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 witness panel. Again, I want to thank you for your patience. For the slightly delayed start. Our first witness today is the Honorable Susan Dudley, Director of the Regulatory Studies Center and Research Professor of Public Policy and Public Administration at the George Washington University. From April, 2007 through January, 2009, Professor Dudley served as the Presidentially-appointed Administrator of the Office of Information and Regulatory Affairs in the U.S. Office of Management and Budget.

The next witness will be Dr. Alan Moghissi, the President of the Institute for Regulatory Science. Previously working for EPA Dr. Moghissi managed numerous programs, including the Bio-Environmental Radiological Program at the National Environmental Research Center in Las Vegas, the Health and Environmental Risk Analysis Program in Washington, DC. He was also the Principle Science Advisor for Radiation and Hazardous Materials and represented the Office of Research and Development in a number of work groups responsible for drafting environmental regulations.

The next witness is Dr. Kenneth Green, a Resident Scholar at the American Enterprise Institute. Dr. Green has studied public policy and regulation at Free Enterprise Think Tanks across North America for nearly 20 years. An environmental scientist by training, Dr. Green focuses on policy and regulations involving energy and environmental health.

And the final witness today is Dr. Gary Marchant, Professor of Law and Executive Director of the Center for Law, Science, and Innovation at Arizona State University. Prior to joining the ASU faculty in 1999, he was a partner in the Washington, DC, law firm, Kirkland & Ellis, where his practice focused on regulatory issues.

Thank you all for appearing before the Subcommittee today. As our witnesses should know, spoken testimony is limited to five minutes each, after which the Members of the Committee will have five minutes each to ask questions.

I now recognize our first witness, Ms. Susan Dudley, Director of the Regulatory Studies Center and Research Professor of Public Policy and Public Administration at the George Washington University.

Ms. Dudley.

STATEMENT OF MS. SUSAN DUDLEY, DIRECTOR, REGULATORY STUDIES CENTER, AND RESEARCH PROFESSOR OF PUBLIC POLICY AND PUBLIC ADMINISTRATION, GEORGE WASHINGTON UNIVERSITY

Ms. DUDLEY. Thank you, Chairman Harris, Ranking Member Miller, and Members of the Subcommittee. As you mentioned I am at G.W. but my remarks here today are my own.

EPA regulations are often the subject of heated debate involving accusations of politicized science and advocacy science. While it is legitimate to be wary of policy officials and politicians trying to influence scientific studies, more often than not, these debates center on issues that science can inform but not decide.

And I am actually going to read a quote from the Bipartisan Policy Center Report that the chairman mentioned. In fact, you read the same quote, but I am going to repeat it again. This is the Bipartisan Policy Center Report, "Improving the Use of Science and Regulatory Policy." " A tendency to frame regulatory issues as debates solely about science, regardless of the actual subject in dispute, is at the root of the stalemate and acrimony all too present in the regulatory system today."

And I do highly recommend that report. I think it does show that these issues are not partisan. Framing issues as debates solely about science is problematic for two reasons.

First, while science is essential for understanding the positive question of what is, it is less helpful for the normative policy question of what should be. Sound policy decisions depend not only on scientific assessments of risk but also on other factors such as economics, ethics, law, and, yes, politics, the will of the people.

Second, scientists will never have complete information to predict outcomes with absolute certainty, so even the risk assessment as opposed to the risk management phase of an analysis depend on assumptions and judgments that guide the use of scientific information.

Policymakers and the public are often unaware of the influence of these risk assessment policy choices or the existence of alternative assessments that are equally plausible. Instead, assessments often generate precise-sounding predictions that hide considerable uncertainty about the actual risk and heavily are influenced by hidden judgments about what policies should look like.

Institutional arrangements in the regulatory development process tend to aggravate these problems, perpetuating the charade that policies are based purely on science, insulating experts involved in a particular rulemaking from dissenting views, rein-

forcing preconceptions and biases, and leading to regulatory policy decisions that are not at all transparent.

As the Committee evaluates approaches to address perceived problems in the quality of EPA science, it is important to identify whether the source of the problem is politicians attempting to control science or the politicization of science, or scientists attempting to control policy, something that David Goldston, who was the Executive Director of the Bipartisan Policy Center Project on this and now at NRDC, calls that the scientification of policy.

My own experience supports the Bipartisan Policy Center's conclusion that the latter problem is behind much of the controversy related to science-based regulation. So with that in mind, let me offer three modest recommendations.

One, recognize that science is a positive discipline that can inform but not decide appropriate policy. Avoid the temptation to delegate decisions to agencies on the pretense that science alone can make the normative decision of what the policy should be. I was going to quote again from the Bipartisan Policy Center report, but I won't in the interest of time.

My second recommendation to recognize that risk assessment necessarily involves assumptions and judgments as well as pure scientific inputs and establish procedures and incentives to make more transparent risk assessment inputs in the range of plausible outcomes.

The National Academies of Science has offered numerous recommendations in this regard for improving the quality and transparency of the EPA risk assessment, including in its recent report earlier this year on the formaldehyde IRIS process.

And my final recommendation is to increase the robustness of regulatory science by institutionalizing feedback mechanisms along with checks and balances. The scientific method depends on falsifiable hypotheses, data gathering, dissent, and challenge to ensure objective analysis to minimize bias in the interpretation of results.

Now, no one is truly objective, so institutional reforms that engage and encourage competing views could go a long way to improve the clarity of the risk assessment process and the decisions that depend on scientific input.

President Obama has taken some positive steps in this regard, reinforcing interagency review and calling for more open exchange with the public.

Other successful reforms might involve pre-rulemaking disclosure of risk assessment information to engage broad public comment on the proper choice of studies, models, assumptions, et cetera, long before any policy decisions are framed and positions are set in stone.

And with 1 second left I will stop. Thank you.

[The prepared statement of Ms. Dudley follows:]

PREPARED STATEMENT OF MS. SUSAN DUDLEY, DIRECTOR, REGULATORY STUDIES CENTER, AND RESEARCH PROFESSOR OF PUBLIC POLICY & PUBLIC ADMINISTRATION, THE GEORGE WASHINGTON UNIVERSITY

Chairman Harris, Ranking Member Miller, and Members of the Subcommittee, thank you for inviting me to testify today on "Fostering Quality Science at EPA: Perspectives on Common Sense Reforms." I am Director of the George Washington

University Regulatory Studies Center and Research Professor in the Trachtenberg School of Public Policy and Public Administration. [1]

From April 2007 to January 2009, I oversaw the executive branch regulations of the federal government as Administrator of the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB). I have devoted my career to trying to improve both the framework for developing regulations and our understanding of regulations' effects, and for over three decades have examined regulations from perspectives in government (as both a career civil servant and political appointee), academia, consulting, and the non-profit world.

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EPA regulations intended to address public health and environmental risks depend on scientific information. They are often the subject of heated debate involving accusations of "politicized science" and "advocacy science," as everyone—including scientists and agency officials—wields scientific information in the service of advocacy. While it is legitimate to be wary of politicians or policy officials trying to influence scientific studies, more often than not, these debates center on issues that science can inform, but not decide.

As the Bipartisan Policy Center, in its 2009 report, *Improving the Use of Science in Regulatory Policy,* observed:

> Political decision-makers should never dictate what scientific studies should conclude, and they should base policy on a thorough review of all relevant research and the provisions of the relevant statutes. But some disputes over the "politicization" of science actually arise over differences about policy choices that science can inform, but not determine. (BPC 2009, 4)

Science is rarely sufficient for making policy decisions for two reasons. First, while science is essential for understanding the positive question of *what is*, or predicting what outcomes might derive under different scenarios, it is less helpful for the normative (policy) decisions regarding what *should be*. Sound policy decisions depend not only on scientific assessments of risk, but also on other factors, such as economics, ethics, law, and politics—the will of the people.

Second, scientists will never have complete information to predict outcomes with absolute certainty, so risk assessors use what the National Research Council (NRC 1983) called "risk assessment policy"—assumptions and rules of thumb—to guide the use of scientific information in analyses that inform policy in the face of uncertainty.

> In each step [of the risk assessment process], a number of decision points (components) occur where risk to human health can only be inferred from the available evidence. Both scientific judgments and policy choices may be involved in selecting from among possible inferential bridges, and we have used the term risk assessment policy to differentiate those judgments and choices from the broader social and economic policy issues that are inherent in risk management decisions. (NRC)

Policymakers and the public are often unaware of the influence of these risk assessment policy choices or the existence of alternative assessments that are equally plausible. Instead, assessments often generate precise-sounding predictions that hide considerable uncertainty about the actual risk. Since EPA's stated policy is to err on the side of overstating risk, it relies on one-sided policy choices at each node in the risk assessment process. Policy decisions that are reported as if they are based on science are heavily are influenced by these hidden staff judgments about what policies should be.

While some judgment is necessary to translate scientific evidence into risk assessment, current risk assessment policies lead to distortions in risk estimates and false precision in the presentation of scientific information. This threatens the scientific credibility of the process, hiding rather than making transparent the uncertainty in assessments of risk, putting key policy choices in the hands of staff, and allowing policy makers to avoid making hard decisions.

When questions involving policy judgment and values are falsely characterized as scientific, a small number of people have an effective monopoly on the information that is used and how it is characterized, leading to decisions that are not as accountable or as transparent as they should be. "When regulators purport to rely on

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[1] The George Washington University Regulatory Studies Center raises awareness of regulations' effects with the goal of improving regulatory policy through research, education, and outreach. This statement reflects my views, and does not represent an official position of the GW Regulatory Studies Center or the George Washington University.

science as the sole basis for their policy choices, the real reasons justifying their choices remain hidden from public view." (Coglianese 2009) This is exacerbated by the adversarial nature of rulemaking, and group dynamics that discourage differences of opinion and lead to poor decisions that mask uncertainty and give short shrift to important factors and perspectives.

Institutional arrangements in the regulatory development process tend to aggravate these problems, perpetuating the charade that policies are based purely on science, insulating experts involved in a particular rulemaking from dissenting views, reinforcing preconceptions and biases, and leading to regulatory policy decisions that are not at all transparent.

Statutory mandates, such as those directing EPA to set National Ambient Air Quality Standards (NAAQS) for "criteria pollutants" under the Clean Air Act, can make inevitable the "science charade," where regulatory agencies "camouflag[e] controversial policy decisions as science." (Wagner 1995, 1614) Congress directs EPA to set NAAQS at a level that is "requisite to protect public health with an adequate margin of safety," but restricts the agency from considering key factors, establishing instead the pretense that science is sufficient to determine a single point concentration that is "requisite to protect public health." The courts have reinforced a limited interpretation of the Act, as well as tight deadlines for issuing revised standards. Executive branch career and policy officials respond by developing scientific-sounding explanations to justify one standard over another. Analysts have an incentive to downplay rather than reveal the implications of key risk assessment policy choices, and decision makers point to science as either requiring a new standard or as being so uncertain that a new standard cannot be set. The interagency review process is often truncated by very short timeframes established by the statute and reviewing courts, and constrained by the limited range of options presented by EPA and its Clean Air Science Advisory Committee. Public interveners vigorously defend alternative standards based on their own interpretation of the science.

This has evolved into an adversarial process, characterized by harsh rhetoric in which each party claims the science supports its recommended policy outcome and questions opponents' credibility and motives, rather than a constructive discussion regarding appropriate assumptions and data and the reasonableness of the statutory goal. The real reasons for selecting a non-zero standard are not transparent.

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As the Subcommittee evaluates approaches to address perceived problems with the "quality, usefulness and objectivity of EPA science," it is important to identify whether the source of the problem is:

A. politicians attempting to control science ("politicization of science"), or

B. scientists attempting to control policy ("scientification of policy.")

My own experience supports the BPC conclusion that this latter problem is behind much of the controversy related to science-based regulation, and is the main contributor to the science charade:

> A tendency to frame regulatory issues as debates solely about science, regardless of the actual subject in dispute, is at the root of the stalemate and acrimony all too present in the regulatory system today. (BPC 2009, 10)

Current procedures for developing regulations addressing health and environmental risk blur the lines between science and policy, hindering not only public policy decisions, but development of scientific knowledge itself. Current institutions provide incentives to bury policy judgments in analyses that are presented as science, perpetuating the science charade.

Altering these incentives is challenging, and I appreciate this Subcommittee's interest in this subject. In a chapter of a forthcoming book,[2] my coauthor Professor George Gray and I offer modest suggestions aimed at increasing transparency in regulatory science, strengthening the checks and balances provided by different participants in the rulemaking process, and engaging a broad range of expertise and perspectives to counter the problems insular decision-making brings. Those suggestions are the basis for a few recommendations to the Subcommittee.

1. *Recognize that "science" is a positive discipline that can inform, but not decide, appropriate policy. Avoid the temptation to delegate decisions to agencies on the*

[2] Institutions and Incentives in Regulatory Science, Lexington Books, Jason Johnston ed., forthcoming spring 2012.

pretense that "science" alone can make the normative determination of what policy should be.

The BPC observed:

The first impulse of those concerned with regulatory policy should not be to claim "the science made me do it" or to dismiss or discount scientific results, but rather to publicly discuss the policies and values that legitimately affect how science gets applied in decision making. (BPC 2009, 4)

Distinguishing between science and policy is not always easy or straightforward, and scientists may make choices based on values in the course of their work. Nonetheless, policy debate would be clarified and enhanced if a systematic effort were made to distinguish between questions that can be resolved through scientific judgments and those that involve judgments about values and other matters of policy when regulatory issues comprise both. This transparency would both help force values debates into the open and could limit spurious claims about, and attacks on science. (BPC 2009, 15)

Legislators should also take care to limit the role of scientific advisory panels to advising on science, and not to embed their policy views in their scientific recommendations. The BPC recommended:

In general, scientific advisory panels should not be asked to recommend specific regulatory policies. (BPC 2009, 5)

2. *Recognize that risk assessment necessarily involves assumptions and judgments as well as pure scientific inputs, and establish procedures and incentives to make more transparent risk assessment inputs and the range of plausible outcomes.*

Efforts to identify and characterize the uncertainty in scientific evidence by quantifying the range of outcomes of potential regulatory actions may provide useful data for improving risk assessment policy choices and increasing confidence in decisions.

The BPC recommended:

In presenting the conclusions of literature reviews, agencies and their scientific advisory committees need to be as open and precise as possible in discussing levels of risk and uncertainty. Policy makers should be wary of conclusions about risk that are expressed as a single number. (BPC 2009, 8)

3. *Increase the robustness of regulatory science by institutionalizing feedback mechanisms, checks, and balances.*

Greater transparency in the models, assumptions, and risk assessment policy choices could encourage more open, constructive debate on those choices. The scientific method depends on falsifiable hypotheses, data gathering, dissent, and challenge to ensure objective analysis to minimize bias in the interpretation of results.

No one is truly objective. We all approach problems with our own "priors" and, particularly when faced with new or incomplete information, we tend to look to others in whom we trust to help form our opinions and make decisions. Cass Sunstein's interesting research on "why groups go to extremes" shows that individuals form more extreme views when surrounded by others with similar perspectives. Institutional reforms that engage competing views could go a long way to improve the clarity of the risk assessment process and the decisions that depend on scientific input.

President Obama has built on his predecessors' efforts to provide for interagency review of different aspects of regulatory decisions, including the underlying science. He has directed agencies to encourage an "open exchange of information and perspectives among State, local, and tribal officials, experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole, including relevant scientific and technical findings."

Successful reforms might involve pre-rulemaking disclosure of risk assessment information, to engage broad public comment on the proper choice of studies, models, assumptions, etc. long before any policy decisions are framed, and "positions" established.

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I appreciate this Subcommittee's interest in improving how science informs environmental regulation, and welcome opportunities to discuss the likely effects of different reforms.

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References

- Breyer, S. (1993). *Breaking the vicious circle: toward effective risk regulation.* Harvard Univ Pr.

The Bipartisan Policy Center (2009). *Improving the Use of Science in Regulatory Policy.* http://www.bipartisanpolicy.org/library/report/science-policy-project-final-report

- Coglianese, C. U.S. House of Representatives, The Committee on Science and Technology (2009). Testimony on the role of science in regulatory reform. *http://democrats.science.house.gov/Media/file/Commdocs/hearings/2009/Oversight/30apr/Coglianese—Testimony.pdf*
- National Research Council (1983). *Risk Assessment in the Federal Government: Managing the Process.* National Academy Press.
- Sunstein, C. (2009). *Going to Extremes: How Like Minds Unite and Divide.* Oxford University Pr.
- Wagner, W.E. (1995). *The science charade in toxic risk regulation.* Columbia Law Review, 95(1613).

Chairman HARRIS. Thank you very much.

I now recognize our second witness, Dr. Alan Moghissi, the President of the Institute for Regulatory Science.

STATEMENT OF DR. ALAN MOGHISSI, PRESIDENT, INSTITUTE FOR REGULATORY SCIENCE

Dr. MOGHISSI. Chairman Dr. Harris, Ranking Member Miller, Members of the Subcommittee, as the chairman said my name is Alan Moghissi, and I am the President of Institute for Regulatory Science. We are not for profit organization established in 1985, and we are in Alexandria, Virginia. We are dedicated to the idea that societal decisions notably environmental regulations must be based on what we call best available science, and Mr. Chairman, you used that term, and that was music to my ear.

And we define best available science if you go to our website at www.nars.org, you will find upon the description of BAS, my testimony to you is based on that, however, my—it is—what I am doing today is my personal interpretation of BAS rather than official pronouncement of the Institute for Regulatory Science.

Although the term regulatory science is used extensively in the interest of transparency, let me define it again. Regulatory science consists of the scientific foundation of policy, notably regulatory decisions. It is the science part of the subject rather than societal implications of the regulatory side.

Based on this definition the scientific activity of the EPA are overwhelmingly regulatory science. I appreciate the opportunity to testify before your Committee, and I am proposing the Congress to enact the Regulatory Science Sunshine Act, Regulatory Science Sunshine Act as a segment of the EPA Authorization Appropriation or as a separate act.

My written testimony includes metrics for evaluation of regulatory science information and regulatory science ethics. My apologies that I cannot describe them because I needed more than 1 hour to do so, and I have only five minutes.

Please note that the regulatory science information at best in the metrics that I included partially reproducible evolving science and often at lower maturity going all the way to scadon to scientific

judgment or even speculation. A characteristic of the class I just described a partially reproducible evolving science is that although its foundation is proven science and uncontested, it often uses a macolic on the right side described, assumptions, judgment, default data, and values if the relevant data or values aren't all available and most unfortunately as Mr. Chairman pointed out, on occasion it uses societal adjustments that are outside the purview of science.

The proposed Regulatory Science Sunshine Act would require that within the R&D Program EPA makes a concerted effort to double up procedures, processes, and methods for each regulatory science, regulatory decision that is based on or includes science, one, identification of assumptions, judgment, default data, any other similar system used in the regulatory process, identification of potential alternatives, and how the conclusions would be different if an alternative assumption, judgment or similar parameters are used.

Two, description of the content of all mathematical equations in words.

Three, information identified above must be written in a language that is understandable to knowledgeable non-specialists or better yet to an average person.

Clear and unambiguous justification for the inclusion of societal objectives in science rather than addressing societal objectives in the administrative decision process.

And obligation of EPA to comply with ethical requirement of regulatory science.

I am a proud member of the—proud charter member of the EPA and believe that EPA has done an outstanding job in protecting human health and the environment. However, I would be less than frank if I would not express my concern over certain decisions that have had adverse societal including environmental consequences.

There are those in the regulatory science community who believe that members of the other scientific disciplines have settled the general public without difficulties understanding the complex nature of regular—of scientific—of regulations. They are wrong. They are dead wrong.

Quoting Sir Thomas Jefferson as did my boss, Ruckelshaus, "If we think the people are not enlightened enough to exercise their control with a wholesome discretion, the remedy is not to take it away from them but to inform their discretion."

Thank you much.

[The prepared statement of Mr. Moghissi follows:]

PREPARED STATEMENT OF DR. ALAN MOGHISSI, PRESIDENT, INSTITUTE FOR REGULATORY SCIENCE

Chairman Dr. Harris, Ranking Member Miller, and Members of the Subcommittee; I am A. Alan Moghissi, President of Institute for Regulatory Science (RSI). We were established in 1985 as a not-for-profit organization located in Alexandria, VA and. We are dedicated to the idea that societal decisions notably environmental regulations must be based on what we call "Best Available Science" or BAS. I am a proud charter member of the U.S. Environmental Protection Agency (EPA) and believe that EPA has done an outstanding job in protecting human health and the environment but I am less proud that EPA has missed some opportunities to use BAS in its decisions. I appreciate the opportunity to testify before your Committee and intend to suggest that the time has come for the EPA to substantially expand transparency in the scientific foundation of its regulatory activities.

Science at the EPA and the Establishment of Regulatory Science

Looking back at the history when EPA was formed, although there were laws dealing with air, water, and food, the ability of government to adequately regulate emission of toxic agents was limited. For example, there was no law that provided government for regulating manufacturing of chemicals. During that period the Congress quickly passed a number of laws mandating promulgation of regulations at a rapid pace. Upon the formation of the EPA, the managers and scientists at that Agency were faced with the urgent need to promulgate a large number of regulations based on deadlines mandated by legislative actions or judicial decisions. This problem caused the EPA to rely upon the judgment of scientists, short cutting scientific issues, and use their best to meet the deadlines. During this initial phase of the EPA the phrase regulatory science appeared describing the scientific segments or parts of regulations. Meanwhile regulatory science is defined as follows:

Regulatory science consists of the scientific foundation of policy notably regulatory decisions

Regulatory science, sometimes called regulatory sciences, covers many disciplines (Moghissi et al, 2011). It includes regulatory toxicology, regulatory ecology, regulatory hydrology, and regulatory atmospheric sciences, to mention a few. It is no different than other disciplines such as chemistry discipline that covers, inorganic chemistry, organic chemistry, biochemistry, physical chemistry, chemical engineering, and medicinal chemistry, to mention a few.

As expected virtually all regulatory agencies must deal with regulatory science in promulgating their regulations. For example the Food and Drug Administration (FDA) has not only used that term to describe its scientific objectives but also has devoted significant funds for R&D devoted to regulatory science in areas of its regulatory authority. Similarly, the EPA has an extensive regulatory science program both in its R&D and program offices, although that term is not always used in its pronouncements.

With the maturity of the EPA's regulatory process the EPA is provided significant funding for R&D. A discussion of relevancy of EPA's R&D to its mission, the quality of science used in its regulatory process and related issues have been addressed numerous times and most recently, in testimonies before this Committee (Anastas 2011, Trimble 2011, Elkins 2011). Therefore, this testimony will address the transparency issue, a subject that appears to have been insufficiently addressed. As stated above, during its initial phases of operation, EPA was facing deadlines and had to go through shortcuts. Meanwhile, the EPA has time to thoroughly evaluate the scientific foundation of its regulations. An example of these regulations is emission limits being considered for greenhouse gases. EPA did not face a deadline and based on its own desire undertook the laborious and highly contested decision to regulate greenhouse gases.

Subsequent to the formulation of the term regulatory science, my colleagues and I tried to develop a systematic process for evaluation of regulatory science information. We had to identify fundamental principles not only for regulatory science but also for any scientific claim. We had also to address how does an organization including a regulatory agency assesses the reliability of a scientific claim regardless of its origin. We struggled for many years to address the level of maturity of scientific information. Finally, we had to address the issue of science vs. areas outside the purview of science. These efforts took over three decades and have reached sufficient maturity that can be described here.

Metrics for Evaluation of Regulatory Science Information

As stated above, the development of the BAS system and Metrics for Evaluation of Regulatory Science Information (MERSI) derived from BAS was the result of extensive efforts to systematically evaluate a number of issues addressing the needs of a large segment of the affected communities, notably regulatory science. The development of MERSI was the consequence of three previous publications. The first formal effort Best Available Science; Its Evolution, Taxonomy and Applications (Moghissi et al 2008) contained the fundamental concept of BAS. The next attempt led to the publication of the book: Best Available Science: Fundamental Metrics for Evaluation of Scientific Claims (Moghissi et al 2010) that in many respect, was the second edition of the first book. A new version of that book by Moghissi and Swetnam is in preparation. During all of these activities the dominant role of independent peer review in regulatory science was unambiguously described. Consequently, it was logical to prepare a book Peer Review and Scientific Assessment: *A Handbook for Funding Organizations, Regulator Agencies and Editors* (Moghissi et al, in press) with significant applicability to regulatory science.

Fundamental Principles of MERSI

Open-Mindedness Principle: This principle implies that the regulatory science community and the general public must be willing to consider new knowledge and new scientific claims.

Skepticism Principle: This principle requires that it is incumbent upon those who make a scientific claim to provide sufficient evidence supporting their claim. The Skepticism Principle provides balance and ensures that the Open-Mindedness principle is not misused.

Universal Scientific Principles: The Universal Scientific Principles are a set of basic principles and standards that apply to virtually all of the scientific disciplines including regulatory sciences.

Transparency Principle: Those who make a scientific claim have not only the intellectual but also the ethical obligation to identify the level of maturity and reliability of each segment, and if societal or other areas outside the purview of science are included in the claim.

Reproducibility Principle: Reproducibility is the proof of validity of any scientific claim, and separates undisputed areas of science from those that include assumptions and interpretations.

Pillar: Classification of Scientific Information

It is well established that science evolves and that new discoveries, advancement of scientific knowledge, and numerous technologies result from the evolution of science. Therefore, it is necessary to classify scientific information (SI) in terms of its level of maturity and its reproducibility.

Class I: Proven SI: This class consists of scientific laws (or principles) and their application. The scientific foundation of information included in this class is understood and meets the requirements of the Reproducibility Principle. Scientific laws or principles are predictable and reliable. As the majority of SI covered in regulatory sciences seldom qualifies as Proven SI, further discussion is not required.

Class II: Evolving SI. The overwhelming majority of scientific advancements and virtually all regulatory science information are included in this class.

Reproducible Evolving SI: Reliable and reproducible information dealing with a subject that is not completely understood constitutes the core of this class. Much of medical science provides a good example of Reproducible Evolving Science. Like Class I (Proven SI) information in this class meets the Reproducibility Principle. However unlike Proven SI, the scientific foundation of information in this class is often either unknown or the knowledge is incomplete.

Partially Reproducible SI: Sometimes referred to as Rationalized SI or Scientific Extrapolation this class includes a large segment of regulatory science information including predictive models. Although it builds upon Proven or Reproducible Evolving SI, it uses assumptions, extrapolations, and default data to derive its results. An important characteristic of this class is its level of reproducibility. Whereas the scientific foundation of this class meets the Reproducibility Principle the choice of assumptions, mathematical processes, default data, and numerous other prerequisites are inherently arbitrary and thus are not necessarily reproducible.

Correlation-Based SI: This class attempts to correlate systematic observations performed in accordance with Universal Scientific Principles to an effect. There is an extensive literature covering this class including a large segment of epidemiology. Experience shows that correlation does not necessarily imply causation and as expected, some correlations have correctly identified their cause but others have proven to be unrelated. A segment of evidence-based medicine belongs to this class.

Hypothesized SI: An organized response to an observation, an idea, or any other initiating thought process constitutes the core of this class. This class seldom if ever has a scientific foundation. Obviously, this class does not comply with the Reproducibility Principle.

SI based on Judgment: In the absence of scientific information, decision makers may call upon scientific experts to make an educated judgment. There is an accepted methodology for this process that involves asking multiple qualified and knowledgeable individuals to answer specific questions and statistically assessing the results. Even so, the results are still tantamount to an educated guess.

Speculation: Speculation does not meet the standards for any of the discussed classes of scientific information addressed above. It is based solely on the opinion and intuition of an individual. Often the objective of speculation is to initiate a research project or stimulate a scientific discussion.

Fallacious Information: Most unfortunately, the scientific community and the general public are often provided fallacious information presented as science. Often called "junk science" or "pseudo science," some of the information provided to the regulators by special interest groups qualifies as fallacious information.

Pillar: Reliability of SI

This Pillar requires a formal and generally acceptable process to categorize the reliability of SI. Consequently, SI is divided into several distinct categories in ascending level of reliability

Category I: Personal Opinions. Expression of views by individuals regardless of their training, experience, and social agenda are seldom reliable.

Category II: Gray Literature. Reports prepared by government agencies, advocacy groups, and others that have not been subjected to an independent peer review are included in this category. Gray Literature is often no more reliable that personal opinion.

Category III: Peer-Reviewed SI. The acceptability of a scientific claim requires that it has been subjected to independent peer review and has passed the strict scrutiny by independent scientific peers. Peer review is a well established process and issued extensively in scientific publications and grant submission. Briefly, an acceptable peer reviewer is an individual who is capable of understanding and performing the project under review with little or no additional study. Furthermore, the reviewer must also be independent and without conflict of interest. Finally, (ASME/RSI2002) those who have a stake in the outcome of the review may not act as reviewers or participate in the selection of the reviewers. Despite its acknowledged shortcomings peer review is the only available mechanism to assess the validity of a scientific claim, aside from reproducing the actual claim.

CategoryIV: Consensus-Processed SI. In the consensus process an expert panel, convened in a manner similar to that described for Review Panels, evaluates the proposed information. Since much of regulatory science falls into the Rationalized, Correlation-Based, or Hypothesized SI, it is not surprising that contradictory information can be found in peer-reviewed literature covering a specific subject. In such cases, the consensus process increases the likelihood that its outcome would be consistent with the information that will result from relevant future studies.

Pillar: Outside the Purview of Science

One of the most often violated requirements of regulatory science is the inclusion of societal objectives, ideology, beliefs, and numerous other non-scientific issues. On occasion, the regulators claim that they must include societal objectives in their scientific activities to be protective of human health, the ecosystem, and numerous other worthwhile goals. What is being overlooked is that all of these goals, as desirable as they might be, are outside the purview of science and must be addressed after the scientific issues have been resolved. The confirmation of this Pillar is provided by the Ruckelshaus Effect (Ruckelshaus 1983, Moghissi et al in press) which states that " . . . all scientists must make it clear when they are speaking as scientists -ex cathedra-and when they are recommending policy they believe should flow from scientific information . . . "

Ethics of Regulatory Science

One of the key issues needing the consideration of legislators and regulators is compliance with ethical principles of regulatory science. Only these principles were only recently formulated, they are readily derivable from ethical principles of virtually all professions notably scientific, engineering, and medical professions.

Principle I:

A scientific issue is settled when anyone with the necessary scientific skills, required equipment, and facilities can reproduce it.

On more than one occasion proponents of an issue claim that "science has spoken" or "science is settled" or several other phrases indicating that the scientific part of a regulatory process has been clarified. In effect, those who make such a claim must

provide evidence that the science is reproducible and in the MERSI system, falls into Proven or Reproducible Evolving SI.

Principle II:

Those who prepare a regulatory science document must provide to the affected community assumptions, judgments, and similar parts in a language understandable to a knowledgeable non-specialist.

This principle includes the consequences of using "assumptions, judgments, and similar parts," the justification of using them, and potential alternatives that were not used. This principle is based on the MERSI principle on transparency. The regulated community, the scientists and their organizations, and the interested members of the public are entitled to know the regulatory science is used in a specific decision.

Principle III:

Regulatory science information must exclude societal objectives thus violation the MERSI Pillar "Areas Outside the Purview of Science."

During the initial phases of the EPA, the need for rapid promulgation of regulations led to "being protective" and included societal judgments in the scientific process. One can argue if during that period those actions were justified. However the inclusion of societal objectives or ant other subject that is included in "areas outside the purview of science" is not justified.

Principle IV:

Regulatory science information is only then acceptable if it has been subjected to independent peer review and the review criteria (questions provided to peer reviewers) include compliance with principles I, II, and III of regulatory science ethics.

There is a consensus within the scientific community that peer review is a prerequisite for acceptability of scientific claims. However, the peer review of regulatory science information is particularly important because of the usage of "assumptions, judgments, and similar parts." It is crucial to ensure that the selection of "assumptions, judgments, and similar parts" is not based on a preconceived desire of the regulatory science participants to promote a specific goal. Similarly, if societal objectives are included in regulatory science information, they should be not only identified but also justified.

Proposed Roadmap for Fostering Quality Science at the EPA

Before addressing the proposed roadmap, it is imperative to recognize that the establishment of the EPA and actions taken by that agency, resulted in a cleaner and healthier environment. It would not be constructive to evaluate the performance of the EPA with the objective to see if EPA could have done a better job. Instead, it is more productive to propose relevant R&D with the objective to improve EPA's performance by enhancing the transparency of the regulatory science used by that agency.

It is proposed to enact the **Regulatory Science Sunshine Act** as a segment of the EPA authorization/Appropriation or as a separate Act. The proposed Act would require that EPA develop processes, procedures, and methods for each regulatory decision that is based on or includes science:

1. Identification of assumption judgments, default data, or other similar systems used in the regulatory process, identification potential alternatives, and how the conclusion would be different if alternative assumptions, judgments, and similar parameters were used.
2. Description of the content of all mathematical formulations in words.
3. The information identified above must be written in a language that is understandable to a knowledgeable non specialist or, better yet, to an average person.
4. Clear and unambiguous justification for the inclusion of societal objectives in science rather than addressing societal objectives in the administrative decision process.
5. Obligation of the EPA to comply with ethical requirements of regulatory science

The **Regulatory Science Sunshine Act** would require that EPA makes a concerted effort to develop relevant processes, procedures, and methods to respond to the needs identified above. As many other regulatory agencies face the same problem, such an effort would also benefit numerous other agencies.

Consequences of Regulatory Science Sunshine Act

The opposition to transparency in regulatory science is based on the following:

1. There are those who believe that the "average citizen" is not educated enough or smart enough to appreciate the intricacies of regulatory science.
2. Some of the staff members of regulatory agencies consider that items identified under Regulatory Science Sunshine Act to be burdensome. After all, whereas scientists in regulatory agencies have a unique competency, others do not have relevant experience and competency.
3. The identification of potential uncertainties would result in the opposition of the public to the relevant regulation. It is being claimed that people would suggest that in view of these uncertainties no money should be spent to promulgate or comply with a specific regulation.
4. Certain lobbyists with access to regulatory agencies prefer the current situation because they can impact the regulations without the remainder of the society having the ability to judge the foundation of decisions without significant efforts.
5. Members of a variety of advocacy groups also prefer the current situation, as long as the political leadership is supporting them.
6. There are numerous other individuals and groups who are either opposed to transparency or do not care one way or another.

A closer look at the items identified indicates that the following issues are legitimate and must be addressed:

Ability of the Public to Follow Regulatory Science: It is true that a segment of population will have difficulties following the intricacies of regulatory science. However, other segments are capable of comprehending the subject. In addition using as my former boss William Ruckelshaus quoted Thomas Jefferson "If we think [the people are] not enlightened enough to exercise their control with a wholesome discretion, the remedy is not to take it from them, but to inform their discretion."

Competency of Regulatory Agency Staff: There is ample evidence indicating that there are scientists outside the regulatory agency who are as competent or more competent in relevant areas of regulatory science than the staff members of the relevant agency. This subject is well recognized by reliance upon peer review.

Decisions Based on Uncertain Scientific Information: By far the most critical issue in the proposed legislation in the legitimate issue of convincing the public that a decision is necessary in the interest of the society. It should be recognized that societal decisions based on incomplete and uncertain scientific information is more common than may appear.

The example of meteorology can be used to demonstrate the point, a discipline that provides short term weather forecasting. Most cities rely upon forecasts on snow and its severity and use them to mobilize the necessary personnel and ensure availability of relevant equipment. Similarly, governmental agencies make decisions on both positive and negative consequences of the predicted rainfall.

Let us use the example of Hurricane Irene to demonstrate the point. Events related to this hurricane started at about August 15, 2011 and a few days later, it became clear that Irene would impact the U.S. The pathway of Irene was modified as the hurricane moved closer and its severity was modified several times from category I to category II and Category III but as Irene landed it was largely category I. Many cities and communities had to make decisions based on the information they received at any given time in every case the information was uncertain and incomplete until Irene landed. Should the decision makers wait until they had complete and fully reliable information? No responsible decision maker would do so. Conversely, often the predicted weather proves to be wrong. How often a sunny day is predicted and how often rain or snow is predicted but the predictions prove to be wrong.

The EPA and other regulatory agencies have the legal and ethical obligation to inform the public to the best of their ability the status of the science used in their regulatory decisions. The information must include assumptions, judgments, the inclusion of default data, and any other information that impacted the scientific aspects of their decision.

Conclusions

The **Regulatory Science Sunshine Act** would require a reorientation of the EPA's R&D with the objective to develop processes, procedures, and methods for

transparency in regulatory decisions. EPA should be required to identify assumptions, judgments, default data, or other similar systems used in the regulatory process, identify potential alternatives, and how the conclusion would be different if alternative assumptions, judgments, and similar parameters were used. In addition, EPA should attempt to describe the content of all mathematical formulations in words. Furthermore, the Act should mandate that EPA makes a concerted effort to describe these activities in a language that is understandable to a knowledgeable non specialist or, better yet, to an average person.

References

Ananstas P. Written testimony before the U.S. House of Representatives; Committee on Science, Space and Technology; Subcommittee on Energy and Environment. (November 17) 2011

ASME/RSI(American Society of Mechanical Engineers/Institute for Regulatory Science) Assessment of Technologies supported by the Office of Science and Technology Department of Energy; Results of peer review for fiscal year New 2002. York, NY, ASME 2002.

Elkins Jr. AA. Fostering quality science at EPA. Statement before the Subcommittee on Energy and Environment, Committee on Science, Space and Technology; U.S. House of Representatives, (November 17) 2011.

Moghissi AA, Straja SR, Love BR, McBride DK, Swentnam M. Best Available Science; its evolution, taxonomy, and application. Arlington, VA:Potomac Institute for Policy Studies; 2008

Moghissi AA, Swentnam M, Love BR, Straja SR. Best Available Science; its evolution, taxonomy, and application, second edition. Arlington, VA: Potomac Institute Press; 2010

Moghissi AA, McBrideDK, Amin MA. Regulatory Sciences: Description of the disciplines ,education, and ethics. Tokyo; Japan Science and Technology Agency, 2011

Moghissi AA, Straja SR, Love BR. Peer review and scientific assessment: A handbook for funding organizations, regulatory agencies, and editors. Cambridge, UK Cambridge University Press (in press)

Moghissi AA, Swetnam M. Best Available Science; A systematic process for the development and application of metrics for evaluation of scientific claims (in preparation)

Ruckelshaus WD. Science, risk, and public policy. Science 221; 1026–1028: 1983

Trimble DC. Environmental Protection Agency; Actions needed to improve planning, coordination, and leadership of EPA laboratories. Testimony before the Subcommittee on Energy and Environment, Committee on Science, Space and Technology; U.S. House of Representatives, (November 17) 2011.

Chairman HARRIS. Thank you very much.

I now recognize our third witness, Dr. Kenneth Green, a Resident Scholar at the American Enterprise Institute.

STATEMENT OF DR. KENNETH GREEN, RESIDENT SCHOLAR, AMERICAN ENTERPRISE INSTITUTE

Dr. GREEN. Thank you. Chairman Harris, Ranking Member Miller, Members of the Subcommittee, I thank you for inviting me to testify today. I am as the chairman said Kenneth Green, a Resident Scholar with the American Enterprise Institute. I am a biologist and environmental policy analyst by training, and I have studied public policy with a science component for about 20 years now, mostly in non-profit and non-partisan public policy research institutions across North America.

My testimony represents only my views and should not be associated or construed as the official position of anybody else, and my spoken testimony is an abstract from the written testimony I sub-

mitted, which is a little bit lengthier, and I wouldn't have time for it today.

For the sake of complete disclosure, I want to mention that verbally what I submitted in my truth in testimony form, I have served as a grant reviewer for the U.S. EPA on three or four occasions and was paid their customary per-diem for participating in such reviews in 2008, and 2009. Other than offering my judgment on the quality and soundness and relevance of potential grant proposals, I had no other involvement with the award process, nor any involvement to my knowledge of any grant recipients or applicants in any way.

In fact, I would like to take a second to compliment EPA on the rigor of the process they use to evaluate these outside grant proposals and innovative grant requests. I was quite impressed with the level of rigor and discipline involved in analyzing the proposals, ranking them, discussing them, the knowledge ability of the panelists and so forth, and I commend that process.

I wish I could say that all of EPA's science-related activities were equally satisfying to think about, but unfortunately, I can't. My own research, both my own research and reading in the literature suggests that EPA has serious problems in the way that it employs scientific information when it assesses both the potential benefits and potential costs of existing and proposed public policies.

As is common in the public health community, EPA's science culture seems highly risk averse, so much so that when confronted with a range of possible risks, they tend to accept assumptions and design protocols, analytical protocols and frameworks in ways that lead to ever-greater estimations of health risk from ever-lower levels of exposure to environmental pollutants. This is sometimes referred to simply as being conservative or precautionary. In a medical context that can be beneficial, and indeed, nobody wants the agency to blithely dismiss risks, but when such artificially-elevated risk estimates are translated into economic estimates of regulatory benefit and cost and used to prioritize agency efforts and activities, the product is increasingly costly regulations that do increasingly little good, or worse in some cases, actually impose costs to society greater than the benefits that they produce.

That is where things diverge from a harmless precautionary exercise into poor public policy, and I think it is a serious problem. Without a sound understanding of the proposed benefits and costs of regulations, it is impossible to have a rational public policy development process.

It is also difficult for agencies without that to determine their regulatory priorities. Thus, even where an agency's proposals might do more harm than good, they can't optimally bring their resources to bear where they can do benefit to secure the biggest bang for the regulatory dollar without wasting public revenues, public resources.

My own experience with EPA is partly back in 1997, when I was looking at the National Ambient Air Quality Standards, and I noticed some of the problems with the way EPA handles risk assessment. While EPA on one hand was saying that, well, if we reduce—we want to stop the reduction of high-level ozone in the atmosphere because that ozone protects people from cataracts and skin cancer,

they did not want to account for that same phenomenon when they said they want to reduce ozone in lower levels of the atmosphere. And yet the reduction of ozone would have the same effect.

So they didn't want to net out the benefits and harm, possible harms of the regulation, and that was pointed out by others, and I think eventually was discussed in the Supreme Court, that you have to do a net assessment of health and risks and benefits.

Others have documented bigger problems. Garrett Vaughn in 2006 examined EPA's claims about the benefits and costs of their air quality regulations and observed that EPA's estimate of having saved the country some $22 trillion through public health protection from 1970 to 1990 would, if accurate, roughly equal the aggregate net worth of all U.S. households in 1990. Vaughn points out that by EPA claims net benefits equal to nearly three times the profits of all U.S. corporations and a return on capital by the EPA regulations of 500 percent, comparing to a seven percent rate return on investment in the private sector.

Economist Anne Smith recently testified to this Committee, Subcommittee, one associated interesting effect of EPA's benefits inflation is that the degree to which it makes the total number of deaths attributable to particulates implausible. EPA's presumption that fully 320,000 deaths in the United States were due to particulate matter in 2005 represents over 13 percent of all deaths in the United States on average. And behind this average is the presumption that in large expanses of the Eastern U.S., between 16 and 22 percent of all deaths in 2005 were due to particulate matter.

The distortions go on, and I could continue, but I am running out of time. I am sure we all agree that protecting the environment is very important. Having grown up with asthma myself in the San Fernando Valley in California, smog capital of North America at the time, I am very aware of the role that poor air quality can play in determining one's quality of life.

But I hope we also agree there is no benefit in overprotection, and there is no benefit in misallocation of resources, and there is no benefit in the misdirection of attention to small risks at the expense of large risks, which we face elsewhere in the economy, and that getting the science right is important.

EPA's use of science tends to overestimate the risks humans face, I believe, and underestimate the cost of compliance and regulations, leading to poor public policy development.

With that I look forward to your questions. Thank you very much.

[The prepared statement of Mr. Green follows:]

PREPARED STATEMENT OF DR. KENNETH GREEN, RESIDENT SCHOLAR, AMERICAN ENTERPRISE INSTITUTE

The views expressed in this testimony are those of the author alone and do not necessarily represent those of the American Enterprise Institute.

Chairman Harris, Ranking Member Miller, Members of the Subcommittee:

Thank you for inviting me to testify today. I am Kenneth P. Green, a Resident Scholar at the American Enterprise Institute.

I am a biologist and environmental policy analyst by training, and I have studied public policies with a science component for nearly 20 years now, mostly at non-profit, non-partisan public policy research institutions across North America. I began career studying air quality regulations in California, and later expanded that

focus to national air quality policy, climate policy, and energy policy, which are inextricably related.

My testimony represents my personal views only, and should not be construed as the official position any other persons or organizations with which I may be affiliated.

For the sake of complete disclosure, I want to mention verbally what I submitted in my "Truth in Testimony" form: I have served as a grant reviewer for the United States Environmental Protection Agency on 3 or 4 occasions, and was paid their customary per-diem for participating in such reviews in 2008 and 2009. Other than offering my judgment on the quality, soundness, relevance, and potential of grant proposals, I had no other involvement with the award process, nor, to my knowledge, have I had any involvement with any grant recipient or applicant in any way.

In fact, I would like to take this opportunity to compliment EPA on the rigor of the process employed for the reviews in which I participated, which involved assessing relatively low-cost research proposals by university researchers and small businesses in the area of environmental technology, energy technology, and related research. The level of professionalism I encountered in my review sessions was refreshing. The reviewers selected were clearly knowledgeable, diverse, and applied serious effort to the analysis of research proposals that sought taxpayer funding. These were satisfying exercises after which I felt confident that, if the EPA followed the conclusions of the reviewers, taxpayer money might provide some net social benefit.

I wish I could say that all of EPA's science-related exercises are equally satisfying to think about, but unfortunately, I cannot. Both my own research and reading in the literature suggests that EPA has serious problems in the way it employs scientific information when it assesses both the potential benefits, and potential costs of existing and proposed public policies.

As is common in the Public Health community, EPA's science-culture seems highly risk-averse, so much so that when confronted with a range of possible risks, they tend to accept assumptions and design analytical protocols and frameworks in ways that lead to ever-greater estimations of health risk from ever-lower levels of pollution exposure. This is sometimes referred to as being "conservative," or "precautionary." In a medical context, this can be beneficial, and indeed, nobody wants an agency to blithely dismiss proclaimed risks to the public health.

However, when such artificially elevated risk estimates are translated into economic estimates of regulatory benefit and cost, the product is increasingly costly regulations that do increasingly little good, or worse, actually imposes costs greater than the benefits it produces.

This is where things diverge from harmless (if excessive) "risk-aversion" into poor public policy, and it is, I think, a serious problem: having a sound understanding of the proposed benefits and costs of regulation is a pre-requisite for rational public policy development.

Without rigorous benefit-cost estimates, it is impossible for an agency to determine regulatory priorities. Thus, even where an agency's proposals might do more harm than good, they cannot optimally bring resources to bear to secure the biggest safety return-on-investment for regulatory investments potentially wasting scarce public tax resources. This applies between agencies as well. If agency A uses methodologies that inflate the risk posed by the things they regulate, they may well draw public resources away from agency B, which uses more scientifically accurate risk-assessment methods.

As researchers such as Anne E. Smith, Garrett A. Vaughn and others have observed, the tendency to overstate risk, leading to over-estimates of regulatory benefits have afflicted what many would consider EPA's most important mission: ensuring that air quality is kept at a level that protects the public health with an adequate margin of safety.

In my own research looking at the proposed 1997 revisions to the National Ambient Air Quality Standards, I noted similar problems. For example, while EPA was arguing that preserving ozone levels in the upper atmosphere offered protection against cataracts and skin cancer caused by UV exposure, they did not account for the fact that ozone anywhere in the atmosphere offers similar protections. Thus, they did not consider that lowering ozone levels would increase some risks while decreasing others.

Others have documented even larger absurdities, and things have not improved over time.

In 2006, Garrett A. Vaughn examined EPA's claims about the benefits and costs of their air quality regulations.

Vaughn points out that the EPA's estimate of having saved the country some $22 trillion dollars through public health protection from 1970 to1990, "If accurate, that sum would equal "roughly the aggregate net worth of all U.S. households in 1990." Vaughn points out that by EPA's self-promoting calculations, "In 1990, for instance, the EPA claims net benefits equal to nearly three times the profits of all U.S. corporations." Given how little EPA claimed its regulations cost, the implication was that "EPA's rate of return on capital exceeded 500%, compared to the private sector's 7 percent." That is an absurd thought which should have triggered an agency "reality check," but clearly did not. [1]

As economist Anne E. Smith recently testified to this Subcommittee [2]:

- EPA is relying to an extreme degree on coincidental "co-benefits" from PM2.5 reductions to create the impression of benefit-cost justification for many air regulations that are not intended to address PM2.5.
- In 2009, EPA vastly increased the levels of mortality risks that it attributes to PM2.5 simply by starting to assign risks to levels of PM2.5 down to zero exposure, thus "creating" risks from ambient exposures that are well within the safe range established by the PM2.5 NAAQS.
- This single change nearly quadrupled the pool of purported US deaths due to PM2.5 that RIAs can now count as "saved" by minor incremental reductions in already-low ambient PM2.5 levels projected under new rules.
- This additional pool of PM2.5-related mortality consists of the most noncredible sort of risk estimate, as it is derived from an assumption that a unit of exposure at PM2.5 levels well below any observed in the epidemiological studies poses just as much risk as a unit of exposure at the higher PM2.5 levels where associations have been detected.
- With this change, EPA is now assuming that 13% to 22% of all deaths in the Eastern U.S. were due to PM2.5 in 2005, and that 25% of all deaths nationwide were due to PM2.5 as recently as 1980.
- The decision to inflate the PM2.5 risk estimates by presuming risks continue down to zero has its greatest impact on co-benefits estimates because—for rules that do not address PM2.5 directly—a much greater share of their incremental reduction of PM2.5 will occur in areas that are already in attainment with the PM2.5 NAAQS (and thus that have PM2.5 levels that EPA has deemed safe). Yet, EPA now attributes about 200,000 more PM2.5-related deaths per year to exposures in those areas.
- If it were viewed as credible that such large effects exist below the level of the PM2.5 NAAQS, the appropriate policy remedy would be to tighten the PM2.5 standard, and not to regulate something else altogether in order to obtain those benefits through "coincidence."

Smith further observed that:

- "One associated and interesting effect of this benefits inflation, however, is the degree to which it makes the total number of deaths attributed to PM2.5 implausible. EPA's presumption that fully 320,000 deaths in the U.S. were "due to PM2.5" in 2005 represents over 13% of all deaths in the U.S. on average. And behind that average is the presumption that in large expanses of the Eastern US, between 16% and 22% of all deaths in 2005 were "due to PM2.5". By extension (although EPA has not reported this calculation), EPA's estimates imply that about 25% of all deaths nationwide were due to PM2.5 as recently as 1980."

I am sure that we all agree that protecting the environment and the health of all Americans is an important pursuit. Having grown up with asthma myself, I'm keenly aware of the role that poor air quality can play in determining one's quality of life.

But I hope we also agree that there is no benefit in over-protection, especially when such over-protection costs society a great deal of money that could be put to better uses elsewhere, such as, in the general economy where it might create jobs, which are also important determinants in people's quality of life.

EPA's use of science tends to systematically over-estimate the risks humans face from environmental exposures to pollutants such as particulate matter. Combined

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[1] Garrett A. Vaughn (2006). "Regulatory Sleight of Hand: How the EPA's Benefit-Cost Analyses Promote More Regulation and Burden Manufacturers. (VA: Manufacturers Alliance)

[2] Anne E. Smith (2011). "Prepared Statement of Anne E. Smith, Ph.D. at a Hearing on"Quality Science for Quality Air" by the Subcommittee on Energy and the Environment , Committee on Science, Space, and Technology, United States House of Representatives, Washington, DC, October 4, 2011

this with under-estimated compliance and regulatory costs, EPA's use of science leads to inefficient use of scarce public resources, and imposes regulatory burdens that may well do more harm than good. To me, this is the core of EPA's science-policy problem, and is probably where any reform efforts should begin.

I thank you again for this opportunity to testify, and look forward to your questions.

Chairman HARRIS. Thank you.

I now recognize our fourth and final witness, Dr. Gary Marchant, Professor of Law and Executive Director of the Center for Law, Science, and Innovation at Arizona State University.

STATEMENT OF DR. GARY MARCHANT,
PROFESSOR OF LAW AND EXECUTIVE DIRECTOR,
CENTER FOR LAW, SCIENCE AND INNOVATION,
ARIZONA STATE UNIVERSITY

Dr. MARCHANT. Thank you, Mr. Chairman Harris and Ranking Member Miller and Members of the Committee. I am delighted to be here. My name is Gary Marchant. As was said I am a law professor at ASU, and I direct our Center for Law, Science, and Innovation, which we bill ourselves as the oldest and largest academic center in the country looking at the intersection of law with science and technology. And one of the major issues we focus on is to try and improve the use of science in various types of legal institutions and decision making, including regulatory agencies. I am delighted to be here.

I really want to make two points today. The first one is the importance of science in our environmental regulatory decision making has never been higher both from the demand and supply side. From the demand side that the easy problems in environmental policy have been addressed, the things we can smell and see with our own eyes and ears and nose. We pretty much have dealt with the problems.

The problems we have left are much more subtle, much more long term, and they really require science to tell us the answers. We are not going to detect it with our own senses. We can't tell as individuals what is a problem of what we are exposed to. We really need science to tell us that.

So science from a demand side has never been in greater need, and then from the supply side we have a lot of new science methods coming forward today of toxicogenomics and biomarkers and model ecosystem effects and so on.

So we are getting a lot of new scientific methods coming into our environmental policy world as well, and the combination of those two I think have made science really critical more than ever before in how we deal with environmental policymaking.

Now, two caveats about that, one, as Ms. Dudley has mentioned, science can't answer the questions. Science is an extremely important input in our environmental decision making, but the decisions that EPA has to make are at the end normative. They incorporate science but a lot of other factors as well.

And the second point is that science is always going to have uncertainty. You know, there is always going to be things we don't know in science that is inherent to science. And so it is almost as important for scientists and science to tell us what we don't know as much as we do know so that the decision makers at EPA and

elsewhere can make informed decisions based on that uncertainty. That is inherent to their decision making.

So my second point is that the context and the institutional environment in which science is dealt with really matters. Science has these norms of how it works in and of itself, of objectivity, of neutrality, of looking at the data and making our decisions based on the data, not on personal values and interests and so on.

And because scientists are humans we never get that perfectly right, but there are different ways in which science is done and different institutional contexts that make a big difference. If you don't believe me, you know, just go into a courtroom these days and watch how science is delivered there. It is completely adversarial, and you are not getting the way science is supposed to be done. They are getting two hired guns on opposite extremes.

What you need is a type of process that encourages sort of the consensual way that science works best, and when it is done in an adversarial or politicized environment, it doesn't work as good as it should.

And so you get two kinds of problems. You get a blending of science and policy, the two overlap, and it is hard to draw the line, what Wendy Wagner has called the Science Charade, often where agencies will explain a decision as a scientific decision that involves a lot of science but also involves some normative decisions that should also be expressly recognized.

And the second one is you get both conscious but even more importantly subconscious change in your view on the science based on the policy preferences of the organization you are in.

So I think both of those are problems that EPA faces because EPA is at root a very political and policy organization. I don't mean that in a derogatory—they have to be that way. They are making these complex decisions that involve science but also politics and policy and values and all kinds of different factors, and they have to work in that sort of messy world. That is not a good world for science, and so the idea I would like you to consider is the idea of creating some kind of separate institution to deal with the science.

This was brought up way back in the '80s, in the so-called Red Book, the National Academy of Science considered that, that it is important to separate the science and the policy but didn't agree we should put them in separate institutions.

But what I would like to suggest is that it might be time to reexamine that, to put the science in a separate organization. I have written a couple of articles I suggest something called an Institute for Scientific Assessments, that would basically do these type of assessments in a neutral organization that runs on a scientific model rather than a more policy-type model. And from the bottom to the top, from the DNA of that organization, it works on the scientific model.

And I think there is a couple of really good examples of that we can look at. The Health Effects Institute here in the United States, Europe created something called the European Food Safety Authority that works that same way, and both of those organizations inculcate sort of scientific values top to bottom, and the result is a product coming out of them that is respected across the board.

And so if we can do that, we can start with this baseline of what science can tell us and what it can't, and then we can go from there and make our political and policy decisions, and if we can do that, I think we will end up with both good science and good regulation.

Thank you.

[The prepared statement of Dr. Marchant follows:]

PREPARED STATEMENT OF DR. GARY MARCHANT, PROFESSOR OF LAW AND EXECUTIVE DIRECTOR, CENTER FOR LAW, SCIENCE & INNOVATION, ARIZONA STATE UNIVERSITY

Good afternoon Mr. Chairman and Members of the Committee. I am Gary Marchant, a tenured Professor of Law at the Sandra Day O'Connor College of Law at Arizona State University. Among other responsibilities, I am the Faculty Director of the Center for Law, Science & Innovation at ASU, the nation's oldest and largest academic center studying the intersection of law with science and technology. One of the central missions of my Center is to promote better use of scientific evidence in legal institutions, including legislatures, regulatory agencies and courts. My testimony today is therefore closely aligned with that mission, although the views expressed here represent my own personal perspective on the question of improving science at EPA.

The Critical Role of Science at EPA

Science plays a critical role in EPA's mission to protect human health and the environment. Over the past couple decades, the agency's focus has shifted from the "low hanging fruit" of obvious pollution problems that we can all see billowing out of pipes and smokestacks to more subtle and uncertain environmental problems that we cannot detect with our own senses. Increasingly we have to rely on science to inform us about the risks (or lack thereof) from chronic exposure to individual (or combinations of) chemicals, low-level exposures to ionizing or electromagnetic radiation, new materials such as nanotechnology, ecological disruptions, and climate change, to name but a handful of the almost unlimited inventory of possible environmental risks. As the demand for scientific inputs into environmental regulatory decision-making has grown, so too has the supply of new scientific models, techniques and methods that could be used in environmental decisions. This trend of an increasing demand for, and the supply of, scientific inputs into environmental regulatory decision-making will surely continue and even accelerate for the foreseeable future.

While science is critical to EPA's decision-making, there are two important caveats about the role of science. First, science alone can rarely if ever decide an environmental issue on its own. While sound science can and should inform the regulatory decision, the ultimate decision on whether, how, and to what level to regulate an environmental problem is an inherently normative decision that goes beyond science.[1] Thus, agency attempts to justify or defend regulatory decisions as being dictated by science is a fallacy that Wendy Wagner and others have described as the "science charade."[2] The second caveat is that, without diminishing the role of science, the practical reality is that science is always full of uncertainties and gaps. Thus, it is almost as important to know what science can't tell us as it is to know what science can tell us.

The Institutional Context of Science

While science is critical to EPA's activities, many have been critical of EPA's treatment of science. Former Deputy Administrator of EPA Robert Sussman wrote: "The bottom line is that nobody likes EPA science. Congress does not like it, the scientific community does not like it, the environmental groups do not like it, and industry certainly does not like it."[3] Even the EPA, in a 1992 assessment of the role of science in its own decision-making, concluded that "EPA science is of uneven

[1] Cary Coglianese and Gary E. Marchant, Shifting Sands: The Limits of Science in Setting Risk Standards, 152 PENN. L. REV. 1255–1360 (2004).

[2] Wendy E. Wagner, The Science Charade in Toxic Risk Regulation, 95 COLUMBIA LAW REVIEW 1613–1723 (1995).

[3] Robert M. Sussman, Science and EPA Decision-making, 12 JOURNAL OF LAW AND POLICY 573–587 (2004).

quality, and the agency's policies and regulations are frequently perceived as lacking a sound scientific foundation."[4]

The central focus of my testimony is that the institutional context in which EPA considers and incorporates science into its regulatory decision-making inevitably tilts, and/or is perceived as tilting, its scientific findings in the direction of the agency's political and policy preferences. Science is not supposed to be influenced by such policy preferences—that is a recipe for the actual and perceived bias and distortion of science. At its ideal, science strives to be as neutral and objective as possible, driven by the data itself rather than extrinsic considerations such as politics, policy preferences, personal values, and bias.[5] The closer science approaches that ideal, the more useful it is, because it is then informing the decision-maker what we know and what we don't know. Of course, since science is a human undertaking, it never achieves its absolute ideal, but my primary comment is that the institutional context in which science is presented and considered is a key factor for how closely science approaches its objective ideal.

When science is addressed in an advocacy or partisan institutional context, it tends to be distorted to fit preferred outcomes, with selective reliance on the data, one-sided inferences and assumptions, and uncertainties dismissed or downplayed. Science much more closely approaches its objective ideal when it is addressed in an institutional context that emphasizes the norms of the scientific community - with a preference for consensus-based decisions, an emphasis on the actual data (especially if it has been peer reviewed and published in good scientific journals), express recognition of the inappropriateness of relying on personal or institutional preferences or interests, and openly acknowledging uncertainties and limitations of the data and resulting findings.

EPA is an inherently partisan and political organization. This statement is not intended to be derogatory or critical. Rather, EPA necessarily and appropriately makes decisions that are based on a messy mix of politics, policy, economics, law, interests, and values, with a clear and important institutional mission to protect the environment and human health. This mixing bowl of facts/policy/values is necessary for making ultimate environmental regulatory decisions, but is not a good environment in which to develop and evaluate science. Of course, EPA should and does also bring science into its decision-making mix, but it would be better if the scientific input injected into that decision-making process was developed in a more objective, reliable, and credible forum than within the political cauldron itself. In other words, it would be best if the science was developed and evaluated separately, and in particular in a separate institutional context, from the more political decision-making process.

This issue of whether and how science should be separated from policy and everything else was addressed in an influential 1983 report by the National Research Council (NRC), which is often referred to as the "Red Book."[6] That report set forth a framework for regulatory risk analysis that has generally been followed ever since by U.S. and many foreign regulatory agencies. A central issue in the report was that of separating risk assessment, a primarily scientific undertaking, from risk management, a more policy-related undertaking. The Red Book found that "[a]t least some of the controversy surrounding regulatory actions has resulted from a blurring of the distinctions between risk assessment policy and risk management policy," and accordingly recommended that "regulatory agencies take steps to establish and maintain a clear conceptual distinction between assessment of risks and consideration of risk management alternatives" (p.3).

While recommending the separation of risk assessment from risk management within a regulatory agency, the NRC report recommended against dividing risk assessment and risk management into separate institutions because of the need for risk assessors and risk managers to communicate with each other. While there are some benefits to integrating science with policy within an institution, there are also clear disadvantages with regard to the objectivity and credibility of science produced from such a hybrid organization. As the role of science becomes ever more important to EPA's mission, and as the perception of EPA's science continues to be skeptical across the political spectrum, it may be time to consider a different model that insti-

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[4] Environmental Protection Agency, Safeguarding the Future: Credible Science, Credible Decisions, Report of the Expert Panel on the Role of Science at EPA. Washington, D.C.: Government Printing Office (1992).

[5] See, e.g., ROBERT K. MERTON, THE SOCIOLOGY OF SCIENCE: THEORETICAL AND EMPIRICAL INVESTIGATIONS. Chicago: Chicago University Press (1973).

[6] NATIONAL RESEARCH COUNCIL, RISK ASSESSMENT AND RISK MANAGEMENT IN THE FEDERAL GOVERNMENT. Washington, D.C.: National Academy Press (1983).

tutionally separates the generation and assessment of science from the application of that science in regulatory decision-making.

Successful Examples of Separating Science from Policy

There are some useful precedents of institutionally separating science from policy-making. Two entities that have been successful in this regard are the Health Effects Institute and the European Food Safety Authority.

The Health Effects Institute (HEI) is a nonprofit corporation created in 1980 to provide independent research on air pollution issues that is co-funded by EPA and the automobile industry. The objective of the HEI was to provide "high-quality, impartial, and relevant science on the health effects of air pollution." [7] Although HEI was initially a purely research organization, it subsequently assumed a secondary function of providing neutral scientific assessments of controversial issues. The HEI's commitment to providing a neutral, objective scientific assessment of controversial air pollution issues, implemented through both its organizational structure and procedures, has made it a highly-regarded and credible "honest broker" on air pollution science. [8]

The European Food Safety Authority (EFSA) was created by the European Union in 2002 to serve as "an independent source of scientific advice and communication on risks associated with the food chain." [9] The structure of EFSA is explicitly based on separating science-based risk assessment and policy-based risk management into separate institutions:

> In the European food safety system, risk assessment is done independently from risk management. As the risk assessor, EFSA produces scientific opinions and advice to provide a sound foundation for European policies and legislation and to support the European Commission, European Parliament and EU Member States in taking effective and timely risk management decisions ... EFSA's most critical commitment is to provide objective and independent science-based advice and clear communication grounded in the most up-to-date scientific information and knowledge. [10]

EFSA therefore provides scientific and risk assessments relating to food safety to the regulatory bodies of the European Union (i.e., the EU Commission and the EU Council of Ministers) as well as individual member nations, and issues such assessments in response to specific requests or "questions" from its "clients." While the EFSA has not been without some controversy, it has generally been perceived as responsible for restoring credibility and public trust to the European regulation of food safety after a series of European food controversies. [11] Again, the primary reason for EFSA's success is an institutional commitment to scientific objectivity, as seen by the commitment in its Mission Statement "to the core standards of scientific excellence, openness, transparency, independence and responsiveness." [12]

A Proposed Institute for Scientific Assessments

To separate institutionally science from policy in environmental regulation decision-making, my colleague Angus Macbeth and I proposed in 2008, as part of the "Breaking the Logjam" project, the creation of an Institute for Scientific Assessments (ISA). [13] I have since elaborated on this proposal in an upcoming chapter written for a new book to be published in 2012 edited by Professor Jason Johnston at the University of Virginia School of Law on the broader topic of improving regulatory science tentatively titled "Institutions and Incentives in Regulatory Science."

The ISA would be an independent, stand-alone scientific assessment body that can provide highly valuable and credible scientific input into the regulatory process. It would be structurally and procedurally designed to limit its activities to scientific

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[7] HEALTH EFFECTS INSTITUTE, ABOUT HEI, http://www.healtheffects.org/about.htm (last visited Aug. 22, 2008).

[8] Terry J. Keating, Lessons from the Recent History of the Health Effects Institute, 26 SCI TECH. HUM. VALUES 409–430 (2001).9 EUROPEAN FOOD SAFETY AUTHORITY, ABOUT EFSA, http://www.efsa.europa.eu/EFSA/efsa__locale-1178620753812__AboutEfsa.htm .

[9]

[10] Id.

[11] See, e.g., Ragnar E. Lofstedt, A European Perspective on the NRC "Red Book," Risk Assessment in the Federal Government: Managing the Process, 9 HUM. & ECOLOGICAL RISK ASSESSMENT 1327, 1332 (2003).

[12] Europeon Food Safety Administration, Management Plan of the European Food Safety Authority for 2008 7 (2007), available at http://www.efsa.europa.eu/cs/BlobServer/DocumentSet/mb__managementplan2008-adopted,3.pdf?ssbinary=true.

[13] Angus Macbeth and Gary Marchant. *Improving the Government's Environmental Science. 17 N.Y.U. ENVTL L.J. 134–169 (2008).*

matters and to resist any temptation to stray into policy advocacy. The ISA would be staffed and managed by full-time federal employee scientists hired using an independent process based on scientific merit, and overseen by an external advisory board that would include prominent national scientific experts, such as the leaders of the National Academy of Sciences (NAS) and the American Association for the Advancement of Science (AAAS).

As Angus Macbeth and I initially described the operation and function of the proposed ISA:

> This new scientific assessment agency would not conduct its own research, but rather would gather, evaluate and assess the existing data in a manner that could be used by a regulatory agency in making decisions. The regulatory agencies could identify questions on which they needed scientific assessments through an annual regulatory agenda, supplemented with ad hoc requests as they arise throughout the year (similar to the EU Commission's requests to EFSA or EPA's occasional requests for scientific reviews by the National Research Council or its own Science Advisory Board). In addition to requesting risk assessments for specific rulemakings, an agency may also request a scientific analysis from the ISA on a more general or cross-cutting issue. Congress could also request a scientific opinion from the ISA, helping to fill the gap in Congressional science advice since the demise of the Office of Technology Assessment in 1995 (pp. 162–163).

In conducting its assessment, the ISA would be committed to following the norms of scientific inquiry as closely as possible, including objectivity, disclosure of uncertainties and competing hypotheses, and consensus-seeking.

As has been the experience with both EFSA and HEI, instilling a culture of scientific objectivity from top to bottom of the organization will be critical to the ISA's success. In my new chapter about the ISA, I describe the potential benefits of the ISA: "*First*, the ISA structure, limiting consideration to scientific data and issue only, would squeeze out much of the perceived or actual political and policy influence currently afflicting regulatory agency science … *Second*, the ISA approach could reduce the "science charade" … Because the ISA would provide a credible independent assessment about what the science does and cannot tell us, it will be much harder for regulatory agencies to camouflage their policy preferences as science. Thus, regulatory decision-making will be more transparent. A *third* potential benefit of the ISA would be to harmonize scientific assessments of the same issue between different federal agencies … "

I also acknowledge in my new chapter that the "creation of an ISA would no doubt raise a number of administrative and procedural issues. For example, what if a regulatory agency wanted to depart from the scientific findings of the ISA? What opportunity would there be for public comment and perhaps even judicial review of ISA assessments? Could a party challenging in court an agency regulation that relied on an ISA assessment raise claims against the ISA assessment on the merits? These and other issues would require careful consideration." However, there are models and approaches to address these implementation issues, and the potential benefits for improving the credibility of EPA's science may justify this type of institutional change.

In summary, a proposed Institute for Scientific Assessments, staffed and designed to follow the scientific model of objectivity, could enhance the utility and credibility of the scientific inputs into EPA's regulatory decisions. Thank you for considering my suggestion, and I will be happy to address any questions you may have.

Chairman HARRIS. Thank you very much for your testimony, and we will start the round of questions—reminding Members Committee rules limit questioning to five minutes.

The chair will at this point will open the round of questions, and I recognize myself for five minutes.

Dr. Marchant, by the way, it is an excellent point, you know. In medicine we have the NIH to do the research. Totally separate, about as not politicized as you get, and then, of course, the information is public and can be interpreted whatever way it needs to be interpreted.

Ms. Dudley, you know, one thing that has kind of bothered me about some of the science that is presented, because we have had science used as justification for policy decisions, and you know, phrases such as, well, you would save up to, you know, 300,000

cases of asthma a year if only you lowered this particulate matter standard or mercury standard or some co-benefit or whatever.

And as scientist, I mean, if I ever made a presentation at a scientific meeting and in my results section I said up to something, I would be laughed off the stage. You know, they want the mean, they want the standard error, the standard error of the mean, standard deviation, whatever.

But you know, with something like that I wasn't—I have only been here a year. I wasn't here at the last round of reductions in pollution, but I will bet you the claim was made that if only we reduced that pollution, asthma will go down by hundreds of thousands of cases a year, and of course, we all know asthma hasn't gone done. It has gone up.

So do you think that more of the agency's science funds should go actually toward retrospective research to figure out whether EPA regulations in the past, what the exact impact has been and whether they have accomplished their environmental and health goals? Because I bet you we go look at some claims made ten years ago about the incidence of asthma if only we could reduce pollution, and we would be very surprised by the lack of result.

Ms. DUDLEY. I think that is a very interesting proposal. I think one thing that is lacking is the feedback mechanism. I think one of the reasons it may be hard to do is that even though there are large benefits, and we would all recognize there are large benefits, they still may not be observable in the number of asthma cases.

For example, we have observed tremendous reductions in lead. We have reduced lead in the atmosphere, we have reduced it in children's blood, and the reason that we do all that is because there is a real link between child blood levels and IQ, and yet even though we have done tremendous things, we can't measure that change in IQ even with huge changes in lead levels.

So it is hard, but I think it is certainly worth doing. I think it is a very intriguing idea.

Chairman HARRIS. Okay. Dr. Marchant, you had said that, you know, that one of the problems is that you would change, you might change the view. Say if you blend two things, you change the view of science based on policy preference, and I got to tell you we have had testimony from the head of research at EPA about, you know, outlining, for instance, the need for hydrofracturing research to figure out if it is safe.

Dr. MARCHANT. Uh-huh.

Chairman HARRIS. And I asked them at the last panel, I said, look. There have been 1.2 million applications of hydrofracturing. Zero incidences of documented drinking water contamination. Now, a scientist would say in my—wearing my hat as my old profession as a physician, we applied the therapy 1.2 million times, and it was good, and it didn't have an adverse consequence, we would call it a miracle drug, and we would sell it everywhere around the world.

Here the EPA scientist says, no. We have to study the safety of it. Is that one incidence where perhaps if you had separated the science from the policy preference we might have a cleaner scientific method or a justification for scientific projects?

Dr. MARCHANT. Possibly. I am not an expert on that particular issue, but I think there is, just as it is human nature that when

you are working for an organization that has a policy mission, which EPA does, that your view of the world is affected by that. Just like when I was a practicing lawyer, it is affected by what client I worked for. My view of the issue is changed when I start working for a client.

There is just a fundamental matter of human nature, and so I might deliberately skew my views to favor my institution, my employer, but even more subtle, which I think a lot of good scientists will have happen to them, even though they try not to have their view intentionally skewed, would be this implicit, this subconscious way of how you look at the world affected by your organization you are in.

And so if your organization is one that says, all we want to know is what the science tells us, don't—we don't care about the policy, you might get a different answer than one that very much has an important policy.

Chairman HARRIS. Yes. Thank you. Dr. Moghissi, you think the EPA's federal, the Scientific Federal Advisory Committee, standing committees, ad hoc panels should be recommending policy decisions in addition to advising of scientific or technical issues, or should there be a firewall between that?

Dr. MOGHISSI. I believe it should be a firewall. As you can see from my accent I wasn't born in Alexandria, Virginia, and believe me I have—where I come from I recall—I was too young during the second World War, but there was a number of exceptionally competent scientists who where when it came to policy issues or came to the societal issues, were frankly stupid. Johannes Stark was an Nobel-prize winning, the Stark Effect in physics, one of the most important ones, and he was a Nazi. How do you explain that?

I believe there is a place for science, and there is a place for policymakers, and I believe it would be bad idea to mix them.

Chairman HARRIS. Okay. Thank you. Let me just ask one last quick question. Dr. Green, you know, testimony—I recall testimony I think it was one panel or two ago that every dollar spent on regulation we have $40 in benefit, economic benefit. I just suggested, well, it is simple. Let us just go and spend a trillion dollars and pay off our debt and then gain some to that.

Do you think part of the problem is that, again, because the testimony in front of the Committee in the past has been, well, you know, you are going to save up to 300,000 of this or up to 10,000 of this, and I don't know what the range is. Maybe the range of the real science was you actually might lose lives, you know, to save lives. I don't know.

Where are they getting these estimates of 30, $40? I mean, how do they come up with something—because when I talk to business people, they know the real cost of regulation, and they say, no. There is a real cost to these regulations. This disparity between what the two opposing philosophies believe, that regulation costs a lot or regulation saves us a lot.

Dr. GREEN. Well, I think you ask an important question, and you raise—use an important word, which is estimates. These are estimates of lives saved, estimates of illness averted, and increasingly as others have pointed out, including Anne Smith, who has testified for your Subcommittee in the past, EPA bases these estimates

on what are called willingness to pay surveys in which they ask people, what would you pay to avoid losing a day at work because your lungs are too tight? What would you pay to not have a case of bronchitis or to not have a case of lung cancer?

And the problem is this willingness to pay surveys, not only do they not make sense when they compare to each other, the evaluations you get from them are often nonsensical, the literature on willingness to pay surveys specifically says that they really are not indicators of what people would actually pay in the real world.

And so you are using a methodology that you are not—you know is not going to get you what you want but representing it as if somebody has actually been challenged to pay. What would you pay, and would you pay more to avoid cancer than you would bronchitis? Well, logically you would say yes, but some of these willingness to pay surveys don't necessarily bear that out.

Chairman HARRIS. Good. Thank you very much.

And I now recognize Mr. Miller and give you a couple extra minutes here.

Mr. MILLER. Don't worry about it overly much, Mr. Chairman.

I am puzzled by the testimony. I think I agree with the fundamental idea that science should not be the only criteria. It should inform decisions that policymakers will apply, the information that comes from science, the ways in which science informs policy, but then there are other criteria, other considerations that come into affect.

But what I did not really get from your testimony is how does that then happen? Ms. Dudley said that she didn't think that the agency should make the decision. The EPA has criteria set by Congress, passed by statute. We are policymakers. Our names actually appear on ballets. It is right in the Constitution, Article 1, and it sets out how to decide what the criteria are and then apply those—apply science to those statutory criteria and reach a result.

If not the agency, who? And on what basis? Ms. Dudley?

Ms. DUDLEY. I didn't mean to say that agencies shouldn't make a decision. I am not sure what I said that led you to suggest that. I certainly think that agencies should make a decision as delegated under the constraints delegated from Congress.

My recommendation was that when Congress delegate authority to agencies, don't do so under the pretense a decision can be made solely based on science. Allow the agency to consider, to be able to separate the science from a policy decision and base the policy on the range of factors that are relevant for making policy.

Mr. MILLER. But those factors should be set out in statute, right, and they should be decided by Congress and then applied by the agency. Isn't that the way you think it should proceed?

Ms. DUDLEY. By Congress and applied by the Executive Branch. Certainly.

Mr. MILLER. Okay.

Ms. DUDLEY. And so my recommendation to you was when delegating to agencies, recognize that there are there are three things to think of. One is the pure science. Then there is the risk assessment that brings together those different assumptions and judgments, make that transparent and separate that from the policy decision.

Mr. MILLER. Okay. I really did not hear from anyone's testimony how to coordinate science and research at the EPA so that it neither creates a bias against regulation or for regulation. How do we make sure that it provides useful, detached information that policymakers who wish to apply all the proper criteria can rely upon? And I did not really hear that.

I know that you have an hour-long presentation, Doctor.

Dr. MOGHISSI. No, no. My apologies if I wasn't clear.

Mr. MILLER. Okay.

Dr. MOGHISSI. It is the responsibility of the scientists to say that is what the science says and the chairman brought it up, he said up to so much blah, blah, blah. What do you mean up to so much? What is the scientists—we have a statistical process. There is a middle point, there is an upper 95 percentile, there is a lower five percentiles. The task of the scientist said this is the science. The administrator in Ruckelshaus is good at it. You go to the public and say me, the administrator, based on the authority provided to me by Congress, I am taking this number, and that is my decision. The hearing process as you will know is a little more complicated than I make it be. In fact, it is, you know, you have to have—announce it on 30 days and so on and so forth.

But he went and said—there was famous hearings in someplace in I think in Seattle or in Tacoma, in which he exactly did that. This is the science. My conclusion from the science is—that is the decision. Like it or not that is my decision.

Mr. MILLER. Any of you really want to address how, in statute, we can revise the ERDDAA statute to make sure that we get the science that does not have a bias one way or the other?

Dr. Green, and the bias should also not be anti-regulatory.

Dr. GREEN. Well, I agree, and far be it from me to tell you how to do you job. I am not a legislator, I never have been.

Mr. MILLER. That is actually what the people at that table do all the time. That is your job.

Dr. GREEN. I will eschew the activity myself. What I would say is there are some problems with transparency that have been mentioned before and transparency and timeliness. One issue I could suggest, for example, when EPA does regulatory impact analyses, I remember in the 1997, revisions to the National Ambient Air Quality Standards, the regulatory impact analysis was not final until after the rules were passed and written.

Therefore, there really was no opportunity for an outside analysis of whether or not you would be getting the right return on investment. That should not be allowed. I don't see where you can allow a draft regulatory impact assessment to be the only assessment available before passing something of such far-reaching consequences.

So, a suggestion of greater transparency and slowing things down. I mean, if you look at the length of the regulations we are getting, the complexity levels, as we say, as was mentioned earlier, the really easy stuff, getting the photochemical smog out of the air, the things you can see. That is done. The things we are working on now are much more complicated and yet the regulatory process has gotten compressed by timelines that are very tight and make it very hard to review and also there are burdens, more obstacles

being placed in people who do the reviews. It is not a career-building activity for you to participate in reviews for the agency, especially when you have to drop everything to scramble to evaluate a rule that is put out the evening before Thanksgiving weekend, which is all too frequently the case as well.

Mr. MILLER. Okay. Using my last minute of my extended time, we will have additional hearings on this subject. We have—the majority and minority have been in conversation, have been in discussions about how to have a balanced panel that will present views on how to amend the statute, how to revise the statute that has been on the books for 30 years now.

And who should be at that table to present the proper range of use? I mean, now, obviously, for various reasons this panel is of one mind, but there are certainly other points of views, and who should be at that table to present the proper range of views for future hearings?

Dr. MARCHANT. I don't think we are of one mind, but I think that it is important to separate out two different issues here, so I am not really talking about the research that EPA does. I am talking about the science that includes some of their own research but a lot of other research and making a regulatory decision.

And those are sort of two different issues. How they do their research, what type of research EPA should do itself intramurally is one set of issues, which I think is what this statute addresses. The issue I address and some of my colleagues here is more how does EPA incorporate science from its own laboratories but also outside those laboratories in making a regulatory decision?

Those are two separate issues. You might want to separate them.

Chairman HARRIS. Thank you very much.

The gentleman from California, Mr. Rohrabacher, is recognized. You want Mr. Hall? It is your turn but—okay. Mr. Rohrabacher.

Mr. ROHRABACHER. All right. Thank you very much.

You know, I would just like to start out by reading a quote from President Eisenhower in his farewell address, and people always look at that address, and I had it—I Googled it up the other night. It is 15 minutes long. I just would recommend taking a look at the insights of this man who helped defeat the Nazis and saved the world from that terrible threat and then came on as leader of our country and did in retrospect a pretty good job as President of the United States. But he had an incredible vision of things that were happening, both before he became President and when he was younger and what it might look like in the future. And he warned us, yes, against the military industrial complex. Everybody knows that. That is a famous part of his speech, but he also spent just as much time warning us about the corruption of science.

And let me read a part of that. "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, as we should, we should also be alert to the equal and opposite danger that public policy could itself become captive of a scientific technological elite."

And we have lots of evidence of that since Eisenhower left, and I just know that we—just in my lifetime I have seen—I remember

when we didn't eat cranberries for Thanksgiving and Christmas because some scientist came up with the idea that it was going to cause cancer. Of course, it didn't cause cancer.

We also, we know that—and these aren't things that are necessarily being done intentionally. Maybe this scientist at that moment thinks it is really important. We have outlawed DDT, and the scientific, all sorts of scientific evidence, and I bet the scientific league got behind this because it became very trendy because bird shells do, indeed, become less able to protect the developing bird with—if DDT is in the environment. But we also know now that DDT kills mosquitoes, yeah, and mosquitoes cause malaria, and by making sure we protected birds, a number of hundreds of thousands of birds, we have condemned millions of children in Africa to a horrible death of malaria.

Just examples like this where, you know, you have got scientists being used basically to determine policy, and a lot of times their policy is wrong. Maybe the science might even be right, but the policy is wrong.

And so I am very sympathetic with Ms. Dudley's suggestion there. I take it from what you are trying to do is trying to separate policy decisions from scientific research so the scientists should just be answering to the policymakers as to what the exact science is. Is that what we are saying here today?

Ms. DUDLEY. I think that is part of it, and that has been accepted since I think it was 1983, when the National Academies of Sciences issued a report that said let us separate the risk assessment from the risk management. So that is part of it, and I think some of our statutes don't allow us to do that.

But I think then the second part is even in a risk assessment—Professor Marchant was talking about this—even in a risk assessment you have pure science but then you also have some of these judgments. And that—you can't totally separate that, but we should at least make transparent where the science ends.

Mr. ROHRABACHER. Well, Malthus was supposedly a scientist. I mean, he was the mathematician of his day, and he gave us a chart that said that the entire world would starve to death 50 years ago if Malthus was correct, and I remember the cyclamates. Remember cyclamates? The industry put hundreds of millions of dollars into developing a synthetic type of sweetener and somebody said, well, it might cause cancer. Then scientists became a trendy thing. They outlawed it, by the way, they never outlawed it in Canada. Ten years after research they found out it wasn't cancer causing and what ended up, what was the problem then? Well, the fact is high fructose corn syrup was developed in-between and put into place, and if you want to add—and most of us know, I hope this isn't trendy science as well, but high fructose corn syrup isn't really good for people. My wife has outlawed it in our household anyway.

So with that said, Mr. Chairman, I want to thank you for making sure you had a secondary follow up because it is the EPA decision making on science that really can affect so many people's lives in a positive way but also in a negative way.

Thank you very much.

Chairman HARRIS. I thank you.

I recognize the gentleman from New York, Mr. Tonko.

Mr. TONKO. Thank you, Mr. Chair. I thank the panelists for appearing before the Committee, and you have all stated your support for environmental protection, but you have also offered harsh criticism for EPA's science and EPA's regulations.

Could you offer specific illustration of one specific example of good regulation and one specific example of bad regulation?

Ms. DUDLEY. Do you want me to start? I will start.

At EPA I would say an example of good regulations was the removal of lead from gasoline. That was one that was really based on clear science and then a clear risk management analysis as well. So the science informed the risk assessment, which informed the risk management regulatory decision, and I think that has brought about dramatic improvements. It is probably the biggest success story at EPA.

I think the Ambient Air Quality Standards are an example of decisions where we do blur the lines between the science and the policy, and that frankly is because the statute says EPA must make its decision based on public health and public health alone, and yet in the analysis there is no way to draw that line. If you have a linear dose response curve that goes to zero, how do you set a standard that is requisite to protect public health and choose anything other than zero?

And so that forces, EPA to kind of wave their hands and make up all kinds of reasons why they are setting a non-zero standard. And so the real reasons for making that decision is obscured.

Mr. TONKO. Dr. Moghissi.

Dr. MOGHISSI. I am glad you asked. The date is 1970-something when the Toxic Substance Control Act was passed, and up to that time there were no regulations relative to manufacturing of chemicals, and for all practical purposes the industry could just release chemicals as they saw fit.

The regulations were excellent. They came at the right time and resulted in limitations of what the chemical industry could do. And they proved to be cost effective, and they were useful.

Let me give you a bad one. The date is about 1990-something. There is a place called Waste Isolation Pilot Plan in New Mexico and in which radioactive waste from reprocessing of weapons transuranic waste is disposed. Now, the way it is set up, transuranic waste and chemical waste, hazardous waste were combined. That is just the way it worked. And the poor guys had to go and open up this highly-radioactive 55—the container and analyze for chemicals, the chemicals disposal facility is intended to, I don't know, maybe a couple of hundred years, Waste Isolation Pilot Plan is intended to—for thousand years. And, yes, they had to do it. And finally my organization based on the request of someone who, some government agency, we developed way back, we developed a panel, which included the guy who wrote hazardous waste regulations, and they said, don't do it. But the EPA had problems and finally the only way it happened was the Congress, through appropriations, said you can't do it.

So that was the end of it, and it saved a lot of human life, a lot of enormous costs. Can you imagine the requests—requirements for opening up the damn, excuse my French, the 55-gallon container

and radioactive waste to analyze for a little Benzene or something like that?

Good two examples.

Mr. TONKO. Dr. Green.

Dr. GREEN. Thank you. I think there are two points. I agree with Susan, first of all, Professor Dudley, that the handling of lead is an example of good regulation. We had an event not that long ago in which that was discussed at some length, and I would say there is also a distinction that needs to be made between early rounds of the National Ambient Air Quality Standards and later rounds, in that you are going to have a greater return on your investment when you are casing high levels of pollutants, and you have higher level effects.

The wisdom of a regulation can go from being good to being bad based on the rounds and evolution of the problem, and a lot of times the regulations are not written with end feedback evolutionary mechanisms in mind to prevent that from happening.

And so I think it is important these things be made. As for things that go wrong, it is not just EPA, but you have things where it is asbestos regulations which required greater exposures that walls had to be torn open that otherwise humans wouldn't be exposed to that created risks for the clean-up workers for example. That would have to be offset against the risks that people might face in exposure to it.

And finally, approach matters, which is I might agree with you that—we might agree on there is a problem. We might even agree that there is a regulatory or a need for the government to intervene to address that problem, but there is choice options. I can go with an eco tax, I could go with a direct emission fee, or I can go with a regulation or a technology standard or picking and choosing an approach or technology approach.

And those are going to have different costs and benefit return on investment profiles as well as influencing people's lives and individual liberty and commercial liberty and so forth.

Dr. MARCHANT. I think most environmental regulations have done more good than harm. My main concern is how they are explained to the public and really at the margins, but I think if you are looking at beneficial ones, you would have to start with the Ambient Air Quality Standards. They have by far the biggest bang that we have spent on them, and particularly I think there is some issues with the ozone one at the margin, but particulate matter and lead and carbon monoxide have all been tremendously beneficial. The Sewage Treatment Program has been tremendously beneficial. So there is a lot of examples of good ones.

There are ones that are bad, and I think it is interesting looking at the bad ones to see where it went wrong, but I mean, my favorite is one, the DC. Circuit struck down a chemical manufacturing versus EPA case a few—about a decade ago where EPA modeled these high-risk chemicals under the Hazardous Air Program and one particular chemical, basically a solid at the modeling characteristics that EPA used, and the company, you know, gave them clear data that that was a fact, that there would be no exposure, and EPA simply ignored it and says, you have got to be regulated like this because we are going to assume that at this level, this tem-

perature you are not a solid, and they was just clearly scientifically wrong, and yet they just went ahead with the regulation anyhow.

And fortunately, the DC. Circuit struck it down as lacking any plausibility in science whatsoever.

Chairman HARRIS. Thank you very much.

The Chairman, Mr. Hall, is recognized.

Chairman HALL. Thank you very much.

Ms. Dudley, you are exactly right when you delegated authority solely on science. I am sure—I think, I don't think that anybody in here disagrees with that, but I know you didn't intend to say that you ignore good and reliable science, and I respect every one of you that are here. You are Professor of Public Policy, Regulatory Science, Enterprise, Center for Law, Science, and Innovation. You are not with the Administration, and I think Dr. Green did his best to compliment the Environmental Protection Agency. I didn't read enough of it. I quit reading it when I gathered that.

Talk just a minute about the EPA. Maybe—I don't know how long ago, but I was here when we passed the Clean Air Act and the Clean Water Act, and we gave the EPA a place in the sun in that legislation and had expectations that they would use science and use other knowledge that was available to them. And it is my opinion that they have deviated from that, and they have deviated it to the extent that it is very damaging to institutions in my district and all across this country.

Dr. Moghissi, in September I sent EPA a letter requesting information on their Integrated Planning Model. You all call it the IPM. This is the model that the agency used to analyze the Cross-State Air Pollution Rule. You are familiar with that, aren't you?

And the assumptions driving this model have never been made public, and their knowledge of the model itself has never been peer reviewed.

Now, how would the IPM model fare if evaluated by the ethics principle of regulatory science that you described in your testimony?

Dr. MOGHISSI. What they would have to do, they would announce the assumptions, every piece of an assumption, and I am familiar with half of them but not all of them, many of those assumptions on the extreme side of the scientific business, they would have to say what would happen if I make a different assumption on the other side of it and but how would the conclusion be different.

That would be subject to independent peer review and if I might add, the peer review says you have to be qualified if you are a peer reviewer. You do not—may have conflict of interest but those who have a stake in the outcome of the peer review may not be peer reviewers nor may participate in the selection of the reviewers.

And in my opinion that is very often violated. Therefore, it is imperative that this Sunshine Act that I am suggesting open up to the public. Let them—if the people know what they are doing as you are suggesting, if the model, the assumptions in the model are described, if the judgments are described, if the—if alternative assumptions on judgments are described, and the conclusions that are from it described, then the role of the science is done. The next step is the Administrator has to go and say, I pick up this because in my opinion this is the right choice. This is my opinion as an Ad-

ministrator of the EPA. That is what I would like to do. It is not poor regulation. It is not anti-regulation. It is just the truth in regulation.

Chairman HALL. How would the IPM model fare if evaluated by the ethics principle or regulatory science that you described in your testimony? How would that be?

Dr. MOGHISSI. Thank you, sir.

Chairman HALL. If you can't knock that one out of the park, I will give you another one in a minute.

Dr. MOGHISSI. In other words, the peer review must say, include in the peer review not I picked up this assumption, I picked up this alternatives, these are why I did it. I did not—if I include societal objective in it, that is why I did it. Could I have done without it? The openness, the transparency is the key issue. Again, it does not change anything in terms of pro regulations or anti regulations.

What it says is you should tell the public. You gentlemen over there are a hell of a lot more qualified on policy than I am, and I am a scientist, and I am not necessarily all that modest, but I am not qualified. You are qualified.

So, therefore, in my opinion these ethical requirements and it took several years to develop them, are very important to comply with.

Chairman HALL. IPM is the model that the agency used to analyze the Cross-State Air Pollution Rule, as you know, and it affected adversely all over this country but it particularly affected an entity in my District at Mount Pleasant, Texas, Luminant case. I think you may be familiar with that, but it cost them 500 jobs almost immediately, and it is my opinion and my opinion alone that there was such an outcry from that and how it affected a lot of other states, not just Luminant, but they began to make some kind of a realization that they might have made a mistake in leaving, in bypassing or ignoring some science in arriving at their opinions.

This—we had an EPA assistant administrator, Gina McCarthy, here before us, and when she was pressed for some reason, she did something there and gave some ruling without her applying the proper science to it, but she gave us the arrogant answer, we are not in the business of creating jobs, and I left her space to make an apology for that in the testimony, but it never came.

And that is what we get from EPA today. Should EPA continue its path to implement the Cross-State Rule given that the IPM model is not peer reviewed and it is not transparent, or should EPA discontinue their current efforts until such a time that the IMP model is peer reviewed and transparent? Is that the way you think they ought to go?

Dr. MOGHISSI. The way to remedy that, sir, to pass the Regulatory Science Sunshine Act to impose upon the EPA they have to be transparent, they have to pass the peer review consistent with the requirement of ethics of the regulatory science.

People are not stupid. The people understand it. The arrogance of some of the science within or in policymaking I know better what is best for the country. No. The people of the United States know what is best for the country, and therefore, the Sunshine Act open up to the public, and again, this is not pro or against regulations. It just opens it up.

Chairman HARRIS. Thank you very much.

Chairman HALL. My time is up. Thank you, Mr. Chairman.

Chairman HARRIS. Thank you very much.

I recognize the gentleman from California, Mr. McNerney.

Mr. MCNERNEY. Thank you, Mr. Chairman. Mr. Chairman, I would like to address one of the issues you bring up often, hydraulic fracturing. The EPA was authorized by Congress in 2010 to open up a study in hydraulic fracturing and its potential impact on groundwater.

Now, maybe you disagree with that decision, but we saw when we were discussing nuclear waste a few weeks before that if the public doesn't buy into a procedure in their district, you are going to end up in courts, there is going to be fights, it is going to go nowhere. And so it was wise, I think, for Congress to authorize the EPA because there is a groundswell of public concern about potential pollution from hydraulic fracturing.

So if we can prove that it is not a problem, that is good. If we can prove it is a problem, it needs to be done, and so I just wanted to address your continued concern about that.

Now, about the issue that we are discussing today, I didn't necessarily disagree with what was said by the panel. I think Ms. Dudley's use of the word, charade, regarding a policy in science was needlessly inflammatory. But, one of the things that I kept hearing was that we need to have science separated from policy. An example we have of that in the 1990s, we have the Office of Technology Assessment did unbiased work, and the then Speaker of the House of Representative, Newt Gingrich, disbanded that organization because in my opinion he didn't like what they were doing.

So separating science and policy is not really possible in this sort of political environment. I don't know exactly where to go from there, but the objective of this hearing to decide how we should empower or enable scientific research to inform regulatory decision making.

Now, one of the things that Ms. Dudley says is—and all of you, I think, really is that science is not certain, and that is for sure. Science is never certain, but there are ways to include probability assessments in scientific judgments, and there are statistical tools that can be used in decision making with uncertainly.

I have been—I am a mathematician, so I am aware of those tools. So what do you say, Ms. Dudley, in terms of using that approach because we can never have absolute certainty in science?

Ms. DUDLEY. I think that is an excellent suggestion, and the National Academies have suggested that regularly to improve the quantitative uncertainty analysis for regulations that are likely to have the biggest impacts. And the reason that is so important is then you make more transparent what the assumptions that are going into that risk assessment are.

So I think that is key.

Mr. MCNERNEY. So we don't have to have absolute certainty. We can't have absolute certainty.

Ms. DUDLEY. Oh, no, you can't.

Mr. MCNERNEY. But we can make decisions in the absence of absolute certainty.

Ms. DUDLEY. Absolutely. I don't think anyone suggests that you have to wait for certainty. In fact, your point is related to the science charade, which I did not mean to be inflammatory. It is actually a phrase that Wendy Wagner coined a decade or so ago in an excellent article. I have been doing some research lately and find that all the incentives in the regulatory system are to perpetuate that charade, and the charade is that when we make the pretenses that something is based solely on science, we are hiding the real decisions.

And what you are suggesting is a way to step back and make that clear: here are our assumptions, and here is the range of assumptions we could have used, and if we do this quantitative uncertainty analysis, that makes transparent for everyone. It is an excellent suggestion.

Mr. MCNERNEY. Okay. Mr. Green.

Dr. GREEN. I think your point is very well taken. It is also important for people to, I think, to understand. Science is provisional and that science has a culture which is rather different than the culture of policy, and that is science is provisional in that everyone understands that a paper that they put out one week can be overturned the next week.

Mr. MCNERNEY. Uh-huh.

Dr. GREEN. And the consequence is simply that somebody goes back to the lab. But once you start entraining the scientific findings into a regulatory process, it is often hard to reverse the train. And so as I was saying before, I think some feedback mechanisms and evolutionary mechanisms that allow for the provisionality of science to feed back and have faster impacts on slowing the train or changing the course of direction would be very important.

One last comment is I think the transparency issue is very important. Proprietary models are a real problem when you have an agency that is running propriety health models or having proprietary data that can't be analyzed by—from outside. It is very hard to assess whether or not the work itself really does reflect science or reflects simply assumptions that are put into models no one can see.

Mr. MCNERNEY. Okay. Mr. Chairman, I yield back.

Chairman HARRIS. Thank you very much.

Yeah. We will have—we have a little more time left, so we are going to have a second round of questions, but it is limited to three minutes per Member, and I will have the first questions of the second round.

Dr. Green, the Federal Advisory Committee Act, which governs EPA's Science Advisory Board and CASAC, the Clean Air Scientific Advisory Committee, requires that advisory peer review panels be, "fairly balanced in terms of the points of view be represented."

However, a recent hearing raised a number of issues related to these panels. For example, five of the seven standing members of CASAC have recently received EPA funds. They are actually direct recipients of funds, and the current CASAC Particulate Matter Review Panel includes nine scientists who had previously recommended lowering the annual standards. So, you know, maybe have a little bit of policy preference there.

Do you think the requirements for scientific, balanced scientific advice is met by these EPA committees at this point in time?

Dr. GREEN. As I have seen them, I am not—I guess the answer I would say is probably not, but the question is how do you best represent balanced points of view, and I think a lot of the times the discussion comes down in the wrong framework. That is it is industry views versus agency views or university views versus private sector views, public sector versus private sector views.

Without a recognition that there is expertise on both sides, the person doing applied chemistry at Kodak or at a chemical company has very detailed, specific information that could inform policy process. The question is do we capture those people who have direct field experience as much as we capture the expertise of people with university experience or agency experience or agency culture or leaning.

From that I have seen of review panels I rarely have seen one as—you were mentioning the—the Ranking Member was mentioning the lack of balance on the panel here. Imbalanced panels seem to be the norm rather than balanced panels.

Chairman HARRIS. Thank you very much. Professor Dudley, earlier this year the U.S. EPA's long-awaited study of formaldehydes toxicity was panned by the National Academy of Sciences panel that sharply disagreed with the agency's conclusions and declared the effort in need of, "substantial revision." The panel stated, and I am quoting from their statement. "Overall the committee found that EPA's draft assessment was not prepared in a logically-consistent fashion, lacks clear links to an underlying conceptual framework, and does not sufficiently document methods and criteria used to identify evidence for selecting and evaluating studies."

Now, NAS added that EPA's chemical assessments have consistently displayed these problems in recent years. How should the EPA modify the Integrated Risk Information System in response to the criticisms that were raised by NAS?

Ms. DUDLEY. I think the NAS report itself gave some very constructive suggestions, and it comes back to the transparency that we have all been talking about, both you and your panel today.

More transparency so that we understand why decisions are made because risk assessments require a lot of those assumptions, including which studies do you choose, which models do you choose, what default assumptions do you use? If we can make that more transparent and perhaps follow Dr. Moghissi's, those steps to make sure that we really do understand the range of assumptions, I think that would address the Academy's concerns.

Chairman HARRIS. Thank you very much.

Mr. Miller.

Mr. MILLER. Ms. Dudley, the IRIS procedures have changed at least three times in the last decade. There was sort of an early Bush Administration procedure, a late Bush Administration procedure that I think you were the principle author of, and then the Obama Administration has developed their own procedures.

The criticisms of the formaldehyde decision or the formaldehyde decision that was criticized by GAO, under which set of procedures was that decision made?

Ms. DUDLEY. First let me say I was not the architect of the procedures. It was EPA who changed the IRIS procedures. And OIRA was not the architect of that.

I am not sure. I am sure it was over time. I don't know that the new procedures will change that because the procedures really were how you do the vetting, interagency and with the public, and that certainly helps. I think bringing, engaging a broader perspective will address some of the concerns, but I won't use all your time.

Mr. MILLER. Dr. Marchant, you discussed institutional biases at EPA and said that it had sorted science and policies and values into one big mess, but there are—there were panels, review panels that—advisory panels that had been established by statute, and I think maybe by EPA on their own, the scientific, to review scientific research activities.

What role can those or do those advisory panels play, those boards play? Are they functioning, and how can they or do they separate science and policy decisions?

Dr. MARCHANT. I think they do help. They are sort of an intermediate step to have sort of an independent scientific check on what the agency is doing to give them advice. I do think they are still somewhat beholden to the agency as opposed to a completely separate and independent institute that is basically made up of career scientists who work for that institute rather than being appointed by an agency.

I also think that those committees should not be making recommendations on policy. I don't think they should be telling the EPA what level to set the standard. They should be telling them what the science is and then it is the agency's job to set the standard. The scientist shouldn't be making those policy decisions. They aren't policy experts.

Mr. MILLER. Okay. Dr. Green, same question to you.

Dr. GREEN. Well, I think Dr. Marchant's point is exactly right, which is you do need review agencies. You need review panels, but it is difficult not to have them be captured or capture the agency that they are associated with if there is some sort of benefit, whether it is a prestige benefit or an influence benefit or a potential grant benefit or any kind of interaction. It is hard to separate those things out.

It's not that it can't be done, but I think that the important thing is that they should simply draw the line in saying, here is what we read the science as. It is all published, it is all public. Here is how we interpret it. Here is what we think the science says is, and it is not our job to say what it should be or what should be done, and they should hand that—that should be clearly—a clearly political decision by the administrative side of the agencies.

We did—but instead we have previous decisions that would defend it as being the decision is dictated or driven by the science. It is science based. It is science driven. The science says we must X, and science can never tell you what to do. It can only tell you what it is.

And so I guess my, one of my—my only suggestion would be that we should ban the phrase, the science says we must, from statutory language entirely, and we might get improvement that way.

Chairman HARRIS. Thank you very much.

The gentleman from California, Mr. Rohrabacher.

Mr. ROHRABACHER. Thank you very much, Mr. Chairman, and let me just note, and again, this is a very—this is not a scientific analysis of what has been said, it might be impacted by my political opinions, but I would suggest that the Office of Technology Assessment was not eliminated by Newt because it was doing things that he didn't like. No. I was here when that happened. We tried to balance the budget, and that was one of the years that we were able to balance the budget by eliminating what we thought were extraneous groups that were not doing—the job that they were doing was not worth the money that was being paid.

In the case of the Office of Technology Assessment, they would often give us their assessment a year or two after we requested it, and it was no longer necessary to hear their opinion, but they weren't doing a good job, and at least that is what those of us who voted to eliminate that part of our budget in order to have a balanced budget.

I also don't believe that there was ever a groundswell of public concern for fracking, that it might impact on the groundwater. There was a groundswell among liberal politicians who controlled the House at that time, again, another scientific expertise by politicians, who wanted to prove that—or who believe in like global warming is caused by CO_2 and that they would do anything they could to prevent more availability of oil and gas because that would create CO_2, which created global warming. Again, a political decision.

Let me ask my one question, which is at a recent hearing I asked Dr. Paul Anastas, I guess you pronounce it. I am sorry if I have mispronounced it. The Assistant Administrator for EPA's Office of Research and Development, and the EPA Science Advisor, I might add, about new regulations for perchlorate, and this was—basically I asked him in the face of decades of scientific work by—from the National Academies and other reputable scientific institutions, saying that no such regulation was needed, why were they moving forward, and his answer simply, well, it implied that a scientific basis was not required for EPA to create regulations.

I would like to hear from the panel just whether or not—we don't have much time, but a yes or no whether you think that—whether or not EPA should require a scientific basis to create a new regulation.

Just a yes or no or whatever your quick thoughts are.

Dr. MOGHISSI. If they want to develop a regulation, which is based on science, that would be absolutely necessary. How else do you do? The gentleman over there, he is a physician. How else do you go and treat someone with medicine if you don't know what the medicine is?

So, therefore, the disease and medicine are related to each other, and therefore, without having the scientific foundation, the regulation is arbitrary.

Dr. GREEN. I would agree with that. I think you need to have a scientific foundation.

That being said, I mean, there could—you could envision in some cases where the science is so clear that something is damaging that

setting the level could be based on other factors than that. You may not actually have to question the science, but I agree. The key thing is if you are going to regulate, you need a rationale for regulation. If it about environmental protection that suggests you have measured something that needs protecting, you determine what needs to be done in order to protect it. All of those are scientific activities, and without them it is hard to see how you have a rationale for your actions as opposed to simply acting randomly. Why couldn't they then just pass any regulation they want to on any subject if there is no rationale and no linkage to their mission?

Mr. ROHRABACHER. All right.

Dr. MARCHANT. I think personally that is a terrible idea to base it not on science, but I am glad that they would explain it. More honestly, if there isn't science to back it up, to be explicit about that rather than trying to say that there is science so now we can all evaluate it and make our own judgment whether that is a good regulation or not, and I would think it wouldn't be if there is no science to back it up.

Mr. ROHRABACHER. Thank you, Mr. Chairman.

Chairman HARRIS. Thank you.

The gentleman from New York, Mr. Tonko.

Mr. TONKO. I am set.

Chairman HARRIS. Thank you. Okay. I want to thank the witnesses for their valuable testimony and the Members for their questions.

The Members of the Subcommittee may have additional questions for the witnesses, and we ask you to respond to those in writing as quickly as possible.

The record will remain open for two weeks for additional comments from Members. The witnesses are excused. Without objection, the hearing is recessed subject to call of the chair to a date to be determined for a second day of testimony for this hearing.

[Whereupon, at 3:40 p.m., the Subcommittee was adjourned.]

Appendix I

Answers to Post-Hearing Questions

ANSWERS TO POST-HEARING QUESTIONS

Responses by Ms. Susan Dudley,
Director, Regulatory Studies Center,
and Research Professor of Public Policy
& Public Administration,
The George Washington University

Questions submitted by Subcommittee Chairman Andy Harris

Q1. We briefly discussed the potential for retrospective "accountability research" to serve as a feedback mechanism about past regulations and their health and environmental outcomes. What steps could be taken to ensure that these targeted reviews fully and usefully evaluate past regulations to inform future decisions?

A1. Agencies face little incentive to conduct retrospective evaluations of the accuracy of ex ante predictions of health or environmental effects resulting from regulatory action. Unlike federal programs that don't get reauthorized if they don't demonstrate success, regulations tend to stay in place absent some new action. Congress could provide incentives for agencies to examine ex post actuarial data of key outcomes (such as children's IQ, mortality rates, etc.) through sunset provisions that linked continued authorization to a demonstration of a regulation's effectiveness. Perhaps a pilot project, where Congress identified a particular regulation or target pollutant and health effect for review, would help EPA develop a methodology for conducting such reviews.

Q2. The Bipartisan Policy Center's 2009 report, "Improving the Use of Science in Regulatory Policy" was mentioned several times during the hearing. This report made several suggestions that may be useful in guiding this Subcommittee's efforts to reform regulatory science, including:

- *"Studies used in the formulation of regulation should be subject to data access requirements equivalent to those under the Data Access Act."*
- *"The process of conducting literature reviews" and "the process of naming advisory committees" should be made more transparent.*
- *"Agencies should avoid turning repeatedly to the same scientists for service on advisory committees."*
- *Executive branch agencies need to "help clarify for both officials and the general public which aspects of disputes are truly about scientific results and which concern policy."*
- *"Policy makers should be wary of conclusions of risk that are expressed as a single number."*
- *"Federal agencies need to experiment with ways to increase the number of scientists who participate in peer review."*
- *"In presenting the conclusions of literature reviews, agencies and their scientific advisory committees need to be as open and precise as possible in discussing levels of risk and uncertainty."*

Do you agree with any or all of these recommendations? Do you have any additional comments or advice in pursuing these goals?

A2. Yes, I agree with these BPC recommendations. Congress could support these (particularly 4th, 5th and 7th bullets) by explicitly recognizing in authorizing statutes that good policy decisions depend on a range of information, and avoid delegating decisions to agencies on the pretense that "science" alone can make the normative determination of what policy should be. To quote further from the BPC report:

- "The first impulse of those concerned with regulatory policy should not be to claim 'the science made me do it' or to dismiss or discount scientific results, but rather to publicly discuss the policies and values that legitimately affect how science gets applied in decision making." (BPC 2009, 4)
- "Distinguishing between science and policy is not always easy or straightforward, and scientists may make choices based on values in the course of their work. Nonetheless, policy debate would be clarified and enhanced if a systematic effort were made to distinguish between questions that can be resolved through scientific judgments and those that involve judgments about values and other matters of policy when regulatory issues comprise both. This transparency would both

help force values debates into the open and could limit spurious claims about, and attacks on science." (BPC 2009, 15)

Legislators should also take care to limit the role of scientific advisory panels to advising on science, and avoid embedding their policy views in their scientific recommendations. I would also highlight the following BPC recommendation:

- "In general, scientific advisory panels should not be asked to recommend specific regulatory policies." (BPC 2009, 5)

Q3. A recent joint report from the EPA's Science Advisory Board and Board of Scientific Councilors recommended that the Agency "include sustainability in its research vision" in order to allow "EPA to adopt sustainability as a core principle to inform decisions and actions." Is this emphasis on sustainability appropriate for EPA's research and science activities?

A3. I am not familiar with this report or recommendation.

Q4. Many of the regulatory activities that EPA is currently undertaking are based upon statutes and priorities from several decades ago. In your view, are we focusing our attention and scientific resources on the most pressing environmental issues? Are there ways that EPA could better prioritize?

A4. A concerted effort to focus resources on the most pressing environmental issues would be a welcome change. In 1987, EPA ranked its regulated activities according to the risks they posed to human health and the environment. It found that the activities that commanded the largest share of federal resources and public dollars were not the ones that posed the greatest risk. However, the allocation of resources tracked public perception of risks very well. (U.S. Environmental Protection Agency. *Unfinished Business: A Comparative Assessment of Environmental Problems.* February 1987) To my knowledge, EPA has not repeated this exercise but it would likely be fruitful.

Q5. Dr. Marchant recommended the Health Effects Institute or the European Food Safety Agency as potential models for conducting independent scientific assessments as an alternative to the current EPA practices. In your experience, are there other governmental or non-governmental organizations that demonstrate characteristics in scientific assessment or R&D that could serve as a useful model for science reform at EPA?

A5. I do not believe that an independent group of risk assessors, insulated from challenge, would address the problems we see in risk assessment in the U.S. While isolating risk assessors might be an appropriate solution to a problem of "politicized science," as the BPC report concluded, "some disputes over the 'politicization' of science actually arise over differences about policy choices that science can inform, but not determine." EPA's Office of Research and Development arguably fits the Marchant model, yet its IRIS process is widely recognized to be broken, with long delays and the perception that policy preferences are embedded in numbers that are presented as purely risk-based assessments.

The peer-review process may offer a better model for reform, where challenge and debate are encouraged, leading to more robust hypothesis testing and more reliable theories.

Q6. Many EPA science activities are housed within regulatory offices. For example, EPA's Office of Air and Radiation (rather than the Office of Research and Development) manages the National Fuel and Vehicle Emissions Laboratory, as well as the National Air and Radiation Environmental Laboratory. In your view, should science activities be organizationally insulated from regulatory activities to ensure objectivity and balance?

A6. The organizational location of the unit doing the analysis is less important than requirements for transparency so that all analyses can be examined from different perspectives and subjected to challenge. Rather than insulating different groups from challenge, analyses should be replicable, transparently distinguish scientific information from assumptions and policy judgments, and be able to withstand legitimate challenge. Further, the use to which the scientific assessments are put influences the quality of the assessment. Assessments that are factors in policy decisions that permit balancing of risks, costs, and benefits (such as conducted under TSCA or FIFRA) are more likely to be transparent and objective than those conducted for decisions for which they will be the deciding factor (such as NAAQS).

Q7. Some scientific information that is disseminated by federal agencies is subject to specific data quality requirements. Are there additional steps that you think

could be taken to ensure that these peer review and data quality guidelines are followed or expanded for important scientific information at EPA?

A7. More conscientious adherence to existing information quality and peer review requirements would improve both the information disseminated and the policy decisions on which that information is based. The most rigorous research I've seen on agency compliance with information quality guidelines is that of Dr. Richard Belzer (a former OIRA analyst). He has found that through FY2010 EPA's average response times were 166 days for petitions and 316 days for appeals. This record is worse than the government as a whole, which has average response times of 148 days and 186 days, respectively. In its information quality guidelines, EPA committed to respond to both petitions and appeals within 90 days. (See his presentations in November and December 2010 here http://www.rbbelzer.com/presentations.html)

Checks and balances from other branches of government (legislative and judicial) could provide needed incentives to follow these guidelines. Agencies might be more responsive if responding were made a nondiscretionary duty, or if there were penalties that came into force automatically for failure to meet reasonable response deadlines. But it's also possible that the quality of agency responses would decline if responding by the deadline were all that mattered to avoid the penalty. Thus, Dr. Belzer argues for incentives that encourage timeliness and quality in agency responses, not one at the expense of the other. He suggests compliance might improve if agencies could correct errors without having to admit that they were wrong.

Q8. Nearly all of EPA's recent Clean Air Act regulations have been justified on the basis of two studies that rely on entirely on data from the American Cancer Society and the so-called Harvard Six Cities Study. Despite the fact that these data sets were developed with government funds and provide the basic Agency justification for costly regulations, they are not publicly-available so they can be analyzed by other scientists. Do you support making this type of information transparent? In your view, would making these underlying data sets available to everyone improve the Agency's regulatory decisions?

A8. Yes, as the BPC report stated, "Studies used in the formulation of regulation should be subject to data access requirements equivalent to those under the Data Access Act." Risk assessments depend on numerous assumptions and choices, so making underlying data available allows results to be replicated and tested under alternative assumptions. It helps decision makers understand the sensitivity of predictions to different assumptions, and improves the rigor of the analysis and the quality of the regulatory decision.

Q9. As you know, the Office of Management and Budget (OMB) defines agency scientific assessments as "highly influential" if they "could have a clear and substantial impact on important public policies with a potential effect of more than $500 million in any one year." Assessments that fall into this category are required to undergo rigorous and transparent peer-review. However, in many instances EPA has refused to designate even obvious assessments as highly influential—such as its greenhouse gas endangerment finding that is the basis for tens of billions in regulatory costs.

Q9 a. In your experience as head of OIRA, how did you apply this test? Do you think the EPA Endangerment Finding constitutes a highly influential assessment, and if so how can Congress better ensure EPA follows standing OMB requirements?

A9 a. The Information Quality Bulletin provides agencies some discretion in defining "highly influential," however EPA's IG recently opined that the endangerment finding should have been designated as such.

Q9 b. At the Subcommittee's November 17th hearing, EPA Assistant Administrator Paul Anastas said that the agency has not yet determined whether its study on hydraulic fracturing would be designated as highly influential. In your view is it advisable for EPA to determine whether a study will be "highly influential" and thus subject to greater peer review before it actually begins to collect and analyze data?

A9 b. Yes. As, OMB's Information Quality Bulletin for Peer Review states with regard to planning for upcoming disseminations: "The agency shall provide its prediction regarding whether the dissemination will be "influential scientific information" or a "highly influential scientific assessment," as the designation can influence the type of peer review to be undertaken."

Responses by Dr. Alan Moghissi,
President, Institute for Regulatory Science

Questions submitted by Subcommittee Chairman Andy Harris

I am greatly honored to have been invited to testify before the Subcommittee on Energy and Environment of the House Committee on Science, Space, and Technology. Your questions and my response to them are as follows:

Q1. The Bipartisan Policy Center's 2009 report, "Improving the Use of Science in Regulatory Policy" was mentioned several times during the hearing. This report made several suggestions that may be useful in guiding this Subcommittee's efforts to reform regulatory science, including:

- *"Studies used in the formulation of regulation should be subject to data access requirements equivalent to those under the Data Access Act."*
- *"The process of conducting literature reviews" and "the process of naming advisory committees" should be made more transparent.*
- *"Agencies should avoid turning repeatedly to the same scientists for service on advisory committees."*
- *Executive branch agencies need to "help clarify for both officials and the general public which aspects of disputes are truly about scientific results and which concern policy."*
- *"Policy makers should be wary of conclusions of risk that are expressed as a single number."*
- *"Federal agencies need to experiment with ways to increase the number of scientists who participate in peer review."*
- *"In presenting the conclusions of literature reviews, agencies and their scientific advisory committees need to be as open and precise as possible in discussing levels of risk and uncertainty."*

Do you agree with any or all of these recommendations? Do you have any additional comments or advice in pursuing these goals?

A1. I am in fundamental agreement with the above items. Before I respond to the question permit me to briefly address certain issues that would simplify my response to this and other questions:

1. It may be recalled that in my testimony on November 30, 2011, I provided a definition for regulatory science which is the generalized version of definition used by various organizations. I also provided five principles as the foundation of Metrics for Evaluation of Regulatory Science Information (MERSI) and three pillars for scientific information (SI) derived from the MERSI principles. Furthermore, my testimony emphasized the need to identify assumptions, judgments, application of default data, and other non-reproducible (NR) segments in SI.

2. A large number of contested decisions of the EPA are traceable to its history and how the regulatory process at the EPA evolved. President Nixon established the EPA in December of 1970 by combining a number of organizations from various federal agencies. Upon its formation, the EPA faced a number of legally mandated deadlines and during the early history of the EPA many laws were enacted or reauthorized including Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA in 1972), Safe Drinking Water act (SDWA in 1974), Toxic Substances Control Act (TSCA in 1976), Clean Water Act (CWA in 1977), and Clean Air Act (CAA in 1977). In the overwhelming majority of cases, the scientific information and supporting data were insufficient to promulgate regulations based on acceptable science. During the Initial Phase of the EPA's history that lasted about one decade, the administrators had no other choice but to use what has become known as Best Available Technical Information (BATI). Although in a few cases, they were able to use Partially Reproducible SI, in the majority of cases they were forced to rely upon SI at lower level of scientific maturity notably judgment of the EPA staff and EPA consultants. In order to be protective of heath and environmental effects of pollutants they chose what they called the "conservative" approach and overestimated, and often significantly overestimated the human health end environmental effects of the pollutant. During this period, the independent peer review process was virtually unknown.

3. The next decade of the EPA's history could be appropriately called the Exploratory Phase. That phase started with the reappointment of William Ruckelshaus by

President Reagan and followed by his successor, Lee Thomas. These administrators attempted to move the scientific foundation of regulator decisions from the Initial Phase to a process that would be scientifically more acceptable. However, during this phase the process used during the Initial Phase continued and the BATI process remained the predominant process at the EPA.

4. I and many other EPA employees had hoped that the Exploratory Phase would quickly come to an end and a final phase would use scientific methods and approaches commonly used in most scientific disciplines. Unfortunately, despite an enormous level of funding; objections by regulated communities; court cases; and reviews and comments by organizations such as National Academies, Bipartisan Policy Center, and Institute for Regulatory Science, EPA has yet to leave the Exploratory Phase and often relies upon BATI that was common during its Initial Phase.

In the following I will try to respond to the items identified in the first question:

Question: "Studies used in the formulation of regulation should be subject to data access requirements equivalent to those under the Data Access Act."

Response: The Data Access Act requires that agencies provide information to those who request it using the Freedom of Information Act (FOIA). Experience shows repeated abuse of FOIA and thus a more appropriate approach would be compliance with Transparency Principle of MERSI. Congress should mandate that all scientific data with the exception of those that would violate laws dealing privacy or national security, should be placed on the Internet so that the entire scientific community could have access to the information and use the data for scientific assessments.

Question: "Agencies should avoid turning repeatedly to the same scientists for service on advisory committees."

Response: As will be described in the response to the question on peer review, it is imperative to ensure that information included in NR/SI is not based on the philosophical, ideological, or other views of an individual. Therefore, it is necessary to avoid seeking repeatedly the services of the same individuals as members of the advisory committees.

Question: Executive branch agencies need to "help clarify for both officials and the general public which aspects of disputes are truly about scientific results and which concern policy."

Response: There is a similarity between the views expressed by the report of the Bipartisan Policy Center of 2009. It may be recalled that the third pillar of MERSI is "areas outside the purview of science." Mixing science with policy and other non-scientific issues is not only undesirable but may have adverse consequences. As sated above, it is imperative to separate science from its policy implications. Whereas properly performed independent peer review can evaluate the validity of scientific claims, and the reasonableness of selection of NR/SI including potential alternatives, a scientific panel is not necessarily qualified to judge the acceptability of chosen policies or identify potential alternatives.

Question: "Policy makers should be wary of conclusions of risk that are expressed as a single number."

Response: This question addresses one of the most important issues that led to my recommendation of passing the Regulatory Science Sunshine Act. During my tenure at the EPA I managed a risk research program which led to the development of the methodology of ecological risk assessment, a process currently used at the EPA but also globally accepted. Risk assessment for human health and ecology consists of several steps including: source assessment; transport and transformation of pollutant leading to exposure assessment; exposure-effect assessment also known as dose-response function; effect assessment; and finally risk characterization. In most cases, the EPA uses the steps following source assessment to regulate emission of pollutants. In every step there are assumption, judgments and numerous other areas that I called NR in the above description. In virtually every step statistical methods can be and often are used. Instead of statistically evaluating the combined uncertainties in various steps, EPA often uses the upper 95th percentile in each step and then combines the values and statistically evaluates the values. In the final step the upper 95th percentile is reported. EPA has all the right to use the upper 95th percentile provided the midpoint and lower 5th percentile are also provided.

Question: "Federal agencies need to experiment with ways to increase the number of scientists who participate in peer review."

Response: One of the fundamental principles governing peer review and scientific assessment is to avoid using an individual repeatedly in these activities. Increasingly, a rule of thumb has been established requiring that an individual who is qualified to be a "peer" may not be used more than three times .The consequence of violating this rule is more significant that it may appear. It may be recalled that scientific foundation of EPA's actions is at best Partially Reproducible SI, and often lower level of scientific maturity going down to SI based on Judgment. In all of these SI classes, there are assumptions, judgments, application of default data and on occasion societal objectives, identified described above as NR/SI. The repeated use of an individual institutionalizes his/her selection of NR/SI and societal objectives.

Question: "On presenting the conclusions of literature reviews, agencies and their scientific advisory committees need to be as open and precise as possible in discussing levels of risk and uncertainty."

Response: In the past and to some extent today, the EPA reviews the existing literature and chooses one or a select number of information as the foundation of the scientific decisions. It is necessary for the EPA to include all information, identify NR/SI and justify the choices.

Q2. A recent joint report from the EPA's Science Advisory Board and Board of Scientific Councilors recommended that the Agency "include sustainability in its research vision" in order to allow "EPA to adopt sustainability as a core principle to inform decisions and actions." Is this emphasis on sustainability appropriate for EPA's research and science activities?

A2. I remember fondly the establishment of the Science Advisory Board. The task of the Board was to provide scientific advice to the EPA managers and review their scientific activities. Although I am unfamiliar with the Board of Scientific Councilors, I presume that their mission is to provide scientific advice. Sustainability is a societal goal much like many other societal goals such as energy independency or global food supply that include environmental considerations. The two scientific organizations would be well advised to consider the statement by William Ruckelshaus who stated " . . . all scientists must make it clear when they are speaking as scientists—ex cathedra—and when they are recommending policy they believe should flow from scientific information.. What we need to hear more of from scientists is science." Much like many other societal goals sustainability is a highly desirable but should be mandated by Congress and not by scientific groups.

Q3. Many of the regulatory activities that EPA is currently undertaking are based upon statues and priorities from several decades ago. In your view, are we focusing our attention and scientific resources on the most pressing environmental issues? Are there ways that EPA could better prioritize?

A3. I believe that currently, the EPA is focusing its efforts including significant resources to activities that have marginal human health and environmental benefits with high-levels of expenditure. By exaggerating the benefits and underestimating the costs EPA tries to justify its decisions. Traditionally, the EPA has attempted to address chemical and radiological agents and has left decisions on microbiological agents to other agencies. EPA would be well advised to address the exceedingly complex microbiological pollution.

Q4. Dr. Marchant recommended the Health Effects Institute or the European Food Safety Agency as potential models for conducting independent scientific assessments as an alternative to the current EPA practices. In your experience, are there other governmental or non-governmental organizations that demonstrate characteristics in scientific assessment or R&D that could serve as a useful model for science reform at EPA?

A4. There is a distinction to be made between performing scientific assessments and having the resulting activity independently peer reviewed. EPA and its contractors are capable of preparing scientific assessments. What is missing is a properly performed independent peer review of the so prepared scientific assessment. The Institute for Regulatory Science has performed over 300 peer reviews for government agencies at federal, state, and local levels and for Congress. In most cases, the oversight of these reviews was performed by a committee established by the American Society of Mechanical Engineers in cooperation with several other professions societies. The critical part of thee reviews was the proper formulation of review criteria

(questions provided to the reviewers).The subject is too complex to be addressed in this response and our upcoming text book on peer review (as references in my testimony) provides details of the peer review requirements.

Q5. Many EPA science activities are housed within regulatory offices. For example, EPA's Office of Air and Radiation (rather than the Office of Research and Development) manages the National Fuel and Vehicle Emissions Laboratory, as well as the National Air and Radiation Environmental Laboratory. In your view, should science activities be organizationally insulated from regulatory activities to ensure objectivity and balance?

A5. As initially designed the sole objective of having scientists and engineers assigned to program offices was to ensure scientific competency within those offices so that scientific issues could be addressed within those offices in promulgation or enforcing regulations. In order for these Individuals to be informed on the technical development, they were permitted to participate in technical activities of their respective professions. If the above-mentioned laboratories or any other laboratory in the EPA is predominantly performing R&D, it should be assigned to the Office of Research and Development.

Q6. Some scientific information that is disseminated by federal agencies is subject to specific data quality requirements. Are there additional steps that you think could be taken to ensure that these peer review and data quality guidelines are followed or expanded for important scientific information at EPA?

A6. As stated several times both in my testimony and in response to question in this document, the scientific foundation of EPA's decision often include assumption, judgments, default data and occasionally societal objectives. Consequently, the review criteria (questions provided to the reviewers) should include the following:

- Are the assumptions (defined as information that cannot be reproduced by any individual with sufficient knowledge and equipment, if required) justified?
- How would the conclusions be different if the assumptions chosen by the EPA would be replaced by other assumptions?
- Are the judgments (as defined under assumptions) justified and would the conclusions be different if the judgment chosen by the EPA would be replaced by other?
- Are the chosen defaults data justified and would the conclusions be different if the default data chosen by the EPA would be replaced by others?
- Has the EPA provided justification for including non-scientific criteria (often justified for being protective) in the science instead of including it in the administrative and policy decisions?

Q7. Nearly all of EPA's recent Clean Air Act Regulations have been justified on the basis of two studies that rely on entirely on data from the American Cancer Society and the so-called Harvard Six Cities Study. Despite the fact that these data sets were developed with government funds and provide the basic Agency justification for costly regulations, they are not publicly-available so that they can be analyzed by other scientists. Do you support making this type of information transparent? In your view, would making these underlying data sets available to everyone improve the Agency's regulatory decisions?

A7. In the interest of transparency, let me start be declaring that the late Ben Ferris, one of the leaders of the Harvard Six City Study, was a friend and I was briefly the project officer for that study. Both studies can be classified as Correlation-Based SI and it is highly likely that other investigators using the same data would come to different conclusions than those reached by the respective authors. I strongly recommend that the raw data from both the Harvard and American Cancer Society studies be placed on the web. There is no justification for not making the raw data available to other scientists.

Responses by Dr. Kenneth P. Green
Resident Scholar,
American Enterprise Institute

Questions submitted by Subcommittee Chairman Andy Harris

The views expressed in this testimony are those of the author alone and do not necessarily represent those of the American Enterprise Institute.

Q1. The Bipartisan Policy Center's 2009 report, "Improving the Use of Science in Regulatory Policy" was mentioned several times during the hearing. This report made several suggestions that may be useful in guiding this Subcommittee's efforts to reform regulatory science, including:

- *"Studies used in the formulation of regulation should be subject to data access requirements equivalent to those under the Data Access Act."*
- *"The process of conducting literature reviews" and "the process of naming advisory committees" should be made more transparent.*
- *"Agencies should avoid turning repeatedly to the same scientists for service on advisory committees."*
- *Executive branch agencies need to "help clarify for both officials and the general public which aspects of disputes are truly about scientific results and which concern policy."*
- *"Policy makers should be wary of conclusions of risk that are expressed as a single number."*
- *"Federal agencies need to experiment with ways to increase the number of scientists who participate in peer review."*
- *"In presenting the conclusions of literature reviews, agencies and their scientific advisory committees need to be as open and precise as possible in discussing levels of risk and uncertainty."*

Do you agree with any or all of these recommendations? Do you have any additional comments or advice in pursuing these goals?

A1. The suggestions of the Bipartisan Policy Center (BPC) referenced in the Subcommittee's follow-up questions have considerable merit. More transparency; more data-sharing; greater diversity of agency reviewers; greater distinctions between scientific findings and value-driven decisions; more accurate descriptions of proposed risks; and greater explanations of uncertainty levels could only lead to better public policy development.

I am not convinced that the BPC's recommendation to "avoid turning repeatedly to the same scientists for service on advisory committees" is either necessary, nor particularly feasible. There are, after all, a limited pool of scientists who will have particular expertise, time, willingness, and capability of giving quality service on a review committee. It seems reasonable that an agency might repeatedly turn to a particular reviewer who has shown a willingness and ability to participate in previous reviews. Should sufficient safeguards be in place to guarantee balanced points of view, avoid conflicts of interest, etc., agencies should, I think, have the discretion to use a person as a "regular" reviewer.

Q2. A recent joint report from the EPA's Science Advisory Board and Board of Scientific Councilors recommended that the Agency "include sustainability in its research vision" in order to allow "EPA to adopt sustainability as a core principle to inform decisions and actions." Is this emphasis on sustainability appropriate for EPA's research and scienceactivities?

A2. EPA's efforts to insert a "sustainability" agenda into their mission is, I believe, politically driven and unwise. I most certainly do not believe that the EPA should "include sustainability in its research vision." "Sustainability" is a highly subjective term in both spatial and temporal domains. One can define actions as sustainable in a region, or with regard to the entire planet. One can define actions as sustainable for a year, a decade, a century, or for eternity. Such a plastic term would grant EPA extremely wide latitude in its ability to regulate activities that are far outside what I feel is its only legitimate function, which is to protect human health and property from damage via environmental contamination. Additionally, arguments about "sustainability," are often used to promote favored technologies at the expense of disfavored technologies, and plays into the hands of both rent-seekers and activist governments. Thus, by declaring fossil fuels "unsustainable," and wind or solar

power "sustainable," EPA could slant the playing field against fossil fuel development (as they already do, to the limits of their abilities).

Q3. Last year you wrote about one specific example of EPA's National Center for Environmental Research providing $1.4 million dollars to recruit people to "dredge through EPA's databases in order to gin up new things for the agency to worry about and possibly regulate." Can you discuss the role of these epidemiological associations in establishing major regulations, and whether EPA-funded research is being overly protective?

A3. In any large set of data, one can search for, and usually find, any number of correlations. In fact, in very large sets of data, such correlations are virtually certain to exist. But correlations do not equal causality, and it's highly likely that researchers dredging through very large data sets will find statistically significant correlations that are not causally related. As the saying goes, ice cream sales correlate with heat-stroke incidence, but that's not because ice cream causes heat stroke, it's because they both correlate with hot weather.

As I wrote in the article you referenced,

"It is one thing for scientists to identify sick populations, and to investigate what it is that might be making them sick. It is another thing entirely to sift through large data bases in order to come up with correlations that may have no causal relationship.

And, ever helpful, EPA gives some examples of what such data-dredging exercises might look like:

For example, while air pollution associations with respiratory and cardiovascular disease have been studied most extensively, evidence is beginning to emerge of possible air pollution impacts on additional health conditions including diabetes, neurological disorders, and reproductive and developmental outcomes. Studies also might evaluate factors that confer increased sensitivity to air pollution effects such as compromised health status, genetic variants, social and neighborhood conditions, higher exposure and others. In addition, some research groups have developed innovative methods and models to characterize exposure that might be applied to health effects analyses in other cohorts to understand whether certain sources or atmospheric components contribute to observed geographic heterogeneity in health-exposure associations.

Further, EPA has specific outcomes in mind. This is not random data dredging, which would be bad enough. This program seeks to fund directional data dredging that looks only for relationships suggesting that exposures to various air pollutants causes harm to human health. In EPA's words:

EPA is interested in research to explain heterogeneity in health responses to air pollutants. Heterogeneity might be explained by: 1) Individual characteristics and other environmental/social conditions that increase the likelihood of an adverse health outcome among a subset of the population. [emphasis mine]

To pay for this innovative regulatory fishing expedition, EPA proposes to give away $1.4 million dollars in portions up to $300,000, for projects that could last up to three years.

Now, there's nothing wrong with trying to ensure that people's health is protected from dangerous air pollutants (in fact, I'd argue that it's a very legitimate function of government), but there is something wrong with organizing taxpayer funded fishing expeditions to probe for new regulatory potential by seeking out obscure relationships in large databases. And those problems are intrinsic to data dredging, an frequently abused form of data mining.

Data dredging, according to Wikipedia, is "the inappropriate (sometimes deliberately so) use of data mining to uncover misleading relationships in data. These relationships may be valid within the test set but have no statistical significance in the wider population." Wikipedia gives a particularly relevant example: "Suppose that observers note that a particular town appears to be a cancer cluster, but lack a firm hypothesis of why this is so. However, they have access to a large amount of demographic data about the town and surrounding area, containing measurements for the area of hundreds or thousands of different variables, mostly uncorrelated. Even if all these variables are independent of the cancer incidence rate, it is highly likely that at least one variable will be significantly correlated with the cancer rate across the area."

Or, as the Congressional Research Office explains (in the context of fishing for terrorists in air-travel databases):

Although data mining can help reveal patterns and relationships, it does not tell the user the value or significance of these patterns. These types of determinations must be made by the user. Similarly, the validity of the patterns discovered is dependent on how they compare to "real world" circumstances. For example, to assess the validity of a data mining application designed to identify potential terrorist suspects in a large pool of individuals, the user may test the model using data that includes information about known terrorists. However, while possibly re-affirming a particular profile, it does not necessarily mean that the application will identify a suspect whose behavior significantly deviates from the original model.

Another limitation of data mining is that while it can identify connections between behaviors and/or variables, it does not necessarily identify a causal relationship. For example, an application may identify that a pattern of behavior, such as the propensity to purchase airline tickets just shortly before the flight is scheduled to depart, is related to characteristics such as income, level of education, and Internet use. However, that does not necessarily indicate that the ticket purchasing behavior is caused by one or more of these variables. In fact, the individual's behavior could be affected by some additional variable(s) such as occupation (the need to make trips on short notice), family status (a sick relative needing care), or a hobby (taking advantage of last minute discounts to visit new destinations).

In other words, with data dredging, it really is a situation of "Seek and ye shall find." It is one thing for scientists to identify sick populations, and to investigate what it is that might be making them sick. It is another thing entirely to sift through large data bases in order to come up with correlations that may have no causal relationship, but that might, nonetheless, cause EPA to spend scarce taxpayer money researching the potential linkage, or worse, to endlessly dredge through databases in search of ever lower, ever more obscure health impacts to justify expanded regulation and EPA intrusion into the economy.

Q4. Many of the regulatory activities that EPA is currently undertaking are based upon statutes and priorities from several decades ago. In your view, are we focusing our attention and scientific resources on the most pressing environmental issues? Are there ways that EPA could better prioritize?

A4. Partly because of regulations, and partly because of the normal march of technology, which leads to greater efficiency and environmental cleanliness, most indicators of environmental quality have improved dramatically in the last 40 years. The lowest hanging fruit of environmental protection have been plucked, the largest risks and degradations mitigated. We now chase after ever smaller risk-reductions, and the EPA seems to think that no pollution of any kind is acceptable anywhere, for even transient moments where no persons are present. A zero-risk and zero-contamination mindset has us spending ever greater sums for ever smaller benefits. Contrary to EPA's self-congratulatory analysis, economists widely recognize that regulation imposes a drag on economic growth. It is never a good idea to waste public funds, but it is unconscionable to do so under the kind of economic conditions we face today. Policy analysts point out that regulations also impose burdens on people and by restricting their liberty, can deprive them of opportunity.

Thus, I think it is very important, as your question mentions, that EPA's activities should focus on areas of greatest environmental risk—and even better, focus on approaches to reducing those highest-risks with as little economic destruction as possible.

Unfortunately, as I mentioned in my testimony, EPA's questionable use of science—particularly risk assessment as it relates to particulate matter and low-dose exposures to various airborne toxics—drives the agency's prioritization and activities.

To quote from my testimony:

As is common in the Public Health community, EPA's science-culture seems highly risk-averse, so much so that when confronted with a range of possible risks, they tend to accept assumptions and design analytical protocols and frameworks in ways that lead to ever-greater estimations of health risk from ever-lower levels of pollution exposure. This is sometimes referred to as being "conservative," or "precautionary." In a medical context, this can be beneficial, and indeed, nobody wants an agency to blithely dismiss proclaimed risks to the public health.

However, when such artificially elevated risk estimates are translated into economic estimates of regulatory benefit and cost, the product is increasingly costly regulations that do increasingly little good, or worse, actually imposes costs greater than the benefits it produces.

This is where things diverge from harmless (if excessive) "risk-aversion" into poor public policy, and it is, I think, a serious problem: having a sound understanding of the proposed benefits and costs of regulation is a prerequisite for rational public policy development.

Without rigorous benefit-cost estimates, it is impossible for an agency to determine regulatory priorities. Thus, even where an agency's proposals might do more harm than good, they cannot optimally bring resources to bear to secure the biggest safety return-on-investment for regulatory investments potentially wasting scarce public tax resources. This applies between agencies as well. If agency A uses methodologies that inflate the risk posed by the things they regulate, they may well draw public resources away from agency B, which uses more scientifically accurate risk-assessment methods.

Q5. Dr. Marchant recommended the Health Effects Institute or the European Food Safety Agency as potential models for conducting independent scientific assessments as an alternative to the current EPA practices. In your experience, are there other governmental or nongovernmental organizations that demonstrate characteristics in scientific assessment or R&D that could serve as a useful model for science reform at EPA?

A5. I have not made a formal study of how agencies other than EPA manage risk assessment, so I will yield to Dr. Marchant on this matter. I believe that other agencies, such as OSHA take a more pragmatic approach to risk assessment, but again, having not formally studied their methdologies, I can not say if they'd do better with environmental risk assessment than does the EPA.

Q6. Many EPA science activities are housed within regulatory offices. For example, EPA's Office of Air and Radiation (rather than the Office of Research and Development),manages the National Fuel and Vehicle Emissions Laboratory, as well as the National Air and Radiation Environmental Laboratory. In your view, should science activities be organizationally insulated from regulatory activities to ensure objectivity and balance?

A6. As I believe I mentioned in my testimony, it seems obvious to me that having too many related functions within one agency is a problem at EPA. Separation of functions such as risk assessment; peer-review of risk assessments; crafting of risk management plans; sponsoring of scientific inquiry related to risks the agency itself has a motivation to regulate; and cost-benefit analysis could only improve the quality of our efforts to manage environmental risk. Just as we know that monopolies lead to reduced competitiveness and lower-quality products over time, the same is true for government agencies and entities.

Q7. Some scientific information that is disseminated by federal agencies is subject to specific data quality requirements. Are there additional steps that you think could be taken to ensure that these peer review and data quality guidelines are followed or expanded for important scientific information at EPA?

A7. In 2009, I testified before the Senate Environment and Public Works Committee on the question of scientific integrity and transparency. This is what I told the Committee:

As more and more of our nation's public policy decisions involve the use of complex scientific information, it becomes more and more important that our policy-making institutions make use of such information in a process that is free of bias, is open to outside review and analysis, allows for the airing of divergent opinion, and is deliberative enough to ensure that the decisions we make are the right ones.

As recent experience has shown, this is not currently the case. Policies intended to mitigate climate change and conventional pollution with the use of corn-ethanol have backfired badly. Rather than reduce greenhouse gas emissions, poorly-thought out ethanol mandates have increased them. Rather than reduce conventional air pollution, corn-ethanol has increased them, along with polluting surface and ground water, contaminating fish stocks with pesticide and herbicide residues, and expanding oceanic dead-zones caused by algae which bloom as they are over-fed by fertilizer run-off from corn agriculture. Most of these problems were raised by non-governmental analysts before the ethanol mandates were passed, but the policymaking process proved opaque to such cautionary voices.

Now, warnings are coming from non-governmental policy analysts and scientists that we may see equally perverse impacts from other forms of renewable energy that are being promoted at breakneck speed through the spending of stimulus money, and pending legislation involving energy and climate change. For example, new scientific reports are validating concerns expressed by energy analysts that con-

centrated solar power systems may have unsustainable water demand and will imperil fragile desert ecosystems.

Warnings that wind turbines are not environmentally benign are being validated as they are found to cause noise pollution, visual blight, bird and bat kills, and potentially harm livestock. One recent study has found that mass transit systems may well produce more pollution than the automobiles and air travel they seek to displace. Left and right, we are seeing failings of our government's policymaking bodies to listen to cautionary voices in the development of public policy dependent on the sound use of scientific information.

The President's memoranda on Transparency and Open Government and on Scientific Integrity are a good start, but they can only be considered a start in the process to ensure that scientific information is used properly in the process of public policy formation.

On the positive side of the ledger, the memoranda correctly identify certain important elements of a transparent process featuring scientific integrity. The President is exactly correct when he says that "political officials should not suppress or alter scientific or technological findings and conclusions."

It is also reassuring to see the President order that "To the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking."

Of particular importance, I think, is the President's declaration that "Government should be participatory." As the President observes, "Public engagement enhances the Government's effectiveness and improves the quality of its decisions. Knowledge is widely disbursed in society, and public officials benefit from having access to that dispersed knowledge."

The President's call for Executive departments and agencies to offer Americans greater opportunities to participate in policymaking processes and to infuse the decision-making process with their "collective expertise and information" is spot on.

But all too often, I have seen an assumption that only scientists working within government, or dependent on governmental grants have worthwhile knowledge to inject into public policy decision-making. There is, I believe, an inherent bias against scientists in the private sector, even though those are often the people who, day by day, in their laboratories, are producing the prescription drugs that save millions, and who develop the technologies that empower billions.

The same is true with regard to the President's (and agency) emphasis on the peer-reviewed literature. As we have discovered through revelations about fraud in the scientific and medical literature, peer-review is no guarantee of accuracy. And often, the keys to publication are in the hands with those who have a vested interest in preserving the theory that gained them the prestige and standing to be considered as peer-reviewers. As a recent article, ironically published in the peer-reviewed journal PLOS Medicine demonstrated, "most claimed research findings are wrong."

The President, Congress, and regulatory agencies should explicitly recognize that there is a legitimate role for non-governmental, independent scientific participation in the public policy decision-making process in terms of both personnel, and the injection of scientific research conducted outside the peer-reviewed literature.

Many times, over my career, I have seen a lack of real opportunity for consultation in the policymaking process. I have seen massive scientific reports issued by state and federal governmental agencies the day before Thanksgiving weekend, or just before the Christmas season, with minimal time allowed for the review of thousand-page scientific summary documents, and only trivial opportunities for meaningful consultation. We may see that again in coming months, where we've been promised the passage of landmark legislation on climate change, just in time for the Independence Day holiday, and many people's summer vacation.

Post-regulatory release of Regulatory Impact Assessments, as was the case with the 1997 revisions to the National Ambient Air Quality Standards, have sometimes made a mockery of the very idea of consultative decision making.

Massive dockets in which thousands of review comments receive little more than blithe dismissals have been common features of governmental decision-making on important scientific issues I have sought to analyze over the last 18 years.

Well-credentialed and experienced scientists have too often been frozen out of consultative processes because they are viewed as tainted by an industrial connection, or because they hold unorthodox views.

In conclusion, the President's memoranda on Transparency and Open Government, and Scientific Integrity are a good step, but only a single step in improving

the way that our government makes use of scientific information at all levels of the decision-making process.

As more and more issues require the use of such information, more attention needs to be paid to reforming the processes by which scientific information is gathered, validated, balanced, summarized, and used to inform the decision-making process.

Finally, it must always be remembered that science may be able to tell us "what is," but it can never tell us "what to do." Science informs—it does not compel. Public policy formation involves the balance of many factors, social, economic, ethics, equity, individual rights, personal responsibility, and more.

Creating openness and transparency in the scientific elements of the decision-making process is important, but that same level of openness, transparency, and consultation should infuse every element of the public policy development process.

Q8. Nearly all of EPA's recent Clean Air Act regulations have been justified on the basis of two studies that rely on entirely on data from the American Cancer Society and the so-called Harvard Six Cities Study. Despite the fact that these data sets were developed with government funds and provide the basic Agency justification for costly regulations, they are not publicly-available so they can be analyzed by other scientists. Do you support making this type of information transparent? In your view, would making these underlying data sets available to everyone improve the Agency's regulatory decisions?

A8. While I understand the need to protect privileged information, and the confidentiality of the doctor-patient relationship, I believe that it is of utmost importance that the key data used to determine risk-assessments be available for independent review: not simply by an institution picked by EPA, or by any given agency, but by anyone who wants to examine the data.

As we have seen with climate change data manipulation in the case of the infamous hockey stick graph, and the revelation of a cliquish mentality on the part of researchers that was clearly to the detriment of our understanding of climate science, outside review is absolutely vital if we are to have confidence in the quality of the data that is being used to formulate far-reaching public policy initiatives.

There is no reason why suitably blinded data could not be made available to allow others to review the validity of the ACS and Harvard 6-Cities studies which, as you point out, are overwhelmingly important in how EPA develops air quality policy.

Responses by Dr. Gary Marchant,
Professor of Law and Executive Director
Center for Law, Science & Innovation,
Arizona State University

Questions submitted by Subcommittee Chairman Andy Harris

Q1. The Bipartisan Policy Center's 2009 report, "Improving the Use of Science in Regulatory Policy" was mentioned several times during the hearing. This report made several suggestions that may be useful in guiding this Subcommittee's efforts to reform regulatory science, including:

- *"Studies used in the formulation of regulation should be subject to data access requirements equivalent to those under the Data Access Act."*
- *"The process of conducting literature reviews" and "the process of naming advisory committees" should be made more transparent.*
- *"Agencies should avoid turning repeatedly to the same scientists for service on advisory committees."*
- *Executive branch agencies need to "help clarify for both officials and the general public which aspects of disputes are truly about scientific results and which concern policy."*
- *"Policy makers should be wary of conclusions of risk that are expressed as a single number."*
- *"Federal agencies need to experiment with ways to increase the number of scientists who participate in peer review."*
- *"In presenting the conclusions of literature reviews, agencies and their scientific advisory committees need to be as open and precise as possible in discussing levels of risk and uncertainty."*

Do you agree with any or all of these recommendations? Do you have any additional comments or advice in pursuing these goals?

A1. I agree with all these recommendations of the Bipartisan Policy Center's report. I think the 4th recommendation listed on the importance of separating science from policy is critical. If the two are mixed together and confused, accountability and oversight, as well as public participation, are undermined. Putting scientific determinations in a separate institution from policy decisions, such as the Institute for Scientific Assessments I have proposed, would achieve this crucial separation.

Q2. A recent joint report from the EPA's Science Advisory Board and Board of Scientific Councilors recommended that the Agency "include sustainability in its research vision" in order to allow "EPA to adopt sustainability as a core principle to inform decisions and actions." Is this emphasis on sustainability appropriate for EPA's research and scienceactivities?

A2. I have not read this report so cannot comment on it specifically. I do believe sustainability, if defined and applied broadly, can provide an appropriate framework for EPA's research program. It would broaden EPA's focus from solely environmental impacts to consider also broader economic and social values and impacts. It could help move EPA from the adversarial, command and control philosophy that was developed in the 1970s to a more collaborative, cooperative paradigm that is more appropriate to the more complex challenges facing us today.

Q3. Many of the regulatory activities that EPA is currently undertaking are based upon statutes and priorities from several decades ago. In your view, are we focusing our attention and scientific resources on the most pressing environmental issues? Are there ways that EPA could better prioritize?

A3. The 1970s-era environmental statutes and regulations are increasing obsolete, and tend to shackle EPA into rigid, media specific, end of pipe controls that no longer represent the current priorities facing the nation. EPA should have more flexibility to explore market, cooperative/partnership, and other innovative approaches to address remaining problems. For example, the EPA Project XL program was a win-win for the environment and companies subject to artificially rigid and narrow regulations. That program was terminated because it was not consistent with the outdated 1970s-era statutes EPA continues to regulate under.

Q4. You proposed the establishment of an "Institute for Scientific Assessment" to conduct R&D that is currently housed within EPA. Please describe which particular

science and R&D activities this Institute could take over from the Agency. In particular, please assess the feasibility of this organization overseeing and conducting: Integrated Risk Information System assessments; integrated science assessments for National Ambient Air Quality Standards; and determinations about research priorities.

A4. The Institute for Scientific Assessments (ISA) as I have proposed it would not oversee research programs, but would conduct scientific assessments. The ISA would conduct assessments such as IRIS evaluations and NAAQS integrated scientific assessments. The results of these assessments would then be forwarded to EPA for its regulatory decisions. As I have proposed it, the ISA would not provide recommendations on research priorities, but it is conceivable that the mission of the ISA could be expanded in that direction.

Q5. Many EPA science activities are housed within regulatory offices. For example, EPA's Office of Air and Radiation (rather than the Office of Research and Development),manages the National Fuel and Vehicle Emissions Laboratory, as well as the National Air and Radiation Environmental Laboratory. In your view, should science activities be organizationally insulated from regulatory activities to ensure objectivity and balance?

A5. Yes, I believe scientific activities should be institutionally separated from regulatory activities. Placing scientific assessments within the institutional context of, and under the control of, regulatory officials has the potential to consciously or subconsciously influence and bias the nature and outcome of the scientific assessments. This is inconsistent with good scientific practice, which should be insulated from political, policy and personal influences as much as practically possible.

Q6. Some scientific information that is disseminated by federal agencies is subject to specific data quality requirements. Are there additional steps that you think could be taken to ensure that these peer review and data quality guidelines are followed or expanded for important scientific information at EPA?

A6. I have two suggestions. The first one would be to place the activities subject to the peer review and data quality guidelines within an institutional context that is familiar with and dedicated to the principles of good scientific practice that are behind the guidelines. I think an organization like the Institute of Scientific Assessments that I have proposed, that is operated and managed from top to bottom by scientists applying scientific methods and customs, would be more likely to take seriously and adhere to the peer review and data quality guidelines. My other suggestion is to make the guidelines enforceable through judicial review. Unless the guidelines have teeth, they are unlikely to be influential in an environment with so many other factors influencing decision-making.

Q7. 1Nearly all of EPA's recent Clean Air Act regulations have been justified on the basis of two studies that rely on entirely on data from the American Cancer Society and the so-called Harvard Six Cities Study. Despite the fact that these data sets were developed with government funds and provide the basic Agency justification for costly regulations; they are not publicly-available so they can be analyzed by other scientists. Do you support making this type of information transparent? In your view, would making these underlying data sets available to everyone improve the Agency's regulatory decisions?

A7. I definitely think the data should be transparent and publicly available. Transparency is a key requirement of science in order to allow scientific findings to be replicated. As one recent review of what makes good science stated: "The essence of good science is repeatability. Different scientists, in different places, at different times, can repeat good science if they follow the same methods and protocols." Dr. Samuel McNaughten, What is Good Science?, Natural Resources & Envt. (ABA), Spring 1999, at 513. A recent special section in the journal Science on the importance of data replication and reproducibility states: "Replication—the confirmation of results and conclusions obtained independently in another—is considered the scientific gold standard ... The importance of replication and reproducibility for scientists is unquestioned. Sometimes attempts to replicate reveal scientific uncertainties. This is one of the main ways that sciences progresses. Unfortunately, in rare instances (compared to the body of scientific work), it can also indicate fraud." B.R. Jasney et al., Again, and Again, and Again ... , Science 234:1225 (Dec. 2, 2011) (citations deleted). If the underlying data are not made available, they cannot be replicated, and thus the scientific validity of the original study cannot be verified.

FOSTERING QUALITY SCIENCE AT EPA: PERSPECTIVES ON COMMON SENSE REFORM—DAY II (PART II)

FRIDAY, FEBRUARY 3, 2012

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON ENERGY AND ENVIRONMENT,
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY,
Washington, DC.

The Subcommittee met, pursuant to call, at 9:52 a.m., in Room 2318 of the Rayburn House Office Building, Hon. Andy Harris [Chairman of the Subcommittee] presiding.

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
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Subcommittee on Energy & Environment

Fostering Quality Science at EPA: Perspectives on Common Sense Reform – Day II

Friday 3, 2012
10:00 a.m. to 12:00 p.m.
2318 Rayburn House Office Building

Witnesses

Mr. Daniel Greenbaum, President and Chief Executive Officer, Health Effects Institute

Dr. Deborah Swackhamer, Professor, Environmental Health Sciences, University of Minnesota, and Chairwoman, EPA Science Advisory Board

Mr. Michael Walls, Vice President, Regulatory and Technical Affairs, American Chemistry Council

Dr. Richard Belzer, President, Regulatory Checkbook

Dr. Jerald Schnoor, Allen S. Henry Chair in Engineering, Department of Civil and Environmental Engineering, University of Iowa

Dr. S. Stanley Young, Assistant Director for Bioinformatics, National Institute of Statistical Sciences

HEARING CHARTER

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

Fostering Quality Science at EPA: Perspectives on Common Sense Reform—Day II

FRIDAY, FEBRUARY 3, 2012
10:00 A.M.—12:00 P.M.
2318 RAYBURN HOUSE OFFICE BUILDING

Purpose

On Friday, February 3, 2012, the Subcommittee on Energy and Environment of the Committee on Science, Space, and Technology will hold a second day of testimony to provide external perspectives on the need to reauthorize and reform science, research, and development activities at the Environmental Protection Agency (EPA); explore the intersection of Agency-supported science and its regulatory mission; and receive focused recommendations to raise the level, quality, usefulness, and objectivity of EPA science, including any necessary changes to the Environmental Research, Development and Demonstration Authorization Act.

Witnesses

- **Mr. Daniel Greenbaum**, President and Chief Executive Officer, Health Effects Institute
- **Dr. Deborah Swackhamer**, Professor, Environmental Health Sciences, University of Minnesota, and Chairwoman, EPA Science Advisory Board
- **Mr. Michael Walls**, Vice President, Regulatory and Technical Affairs, American Chemistry Council
- **Dr. Richard Belzer**, President, Regulatory Checkbook
- **Dr. Jerald Schnoor**, Allen S. Henry Chair in Engineering, Department of Civil and Environmental Engineering, University of Iowa
- **Dr. S. Stanley Young**, Assistant Director for Bioinformatics, National Institute of Statistical Sciences

Background

The Environmental Research, Development, and Demonstration Authorization Act (ERDDA) authorizes research and scientific activities at the Environmental Protection Agency (EPA). Originally enacted in 1976, Congress subsequently passed annual authorizations through fiscal year 1981. In addition to establishing annual authorization levels, these statutes also directed EPA policy in a variety of areas,including establishing the Office of Research and Development (ORD),[1] requiring a five-year environmental R&D plan, and creating EPA's Science Advisory Board (SAB).

Year	Act	Public Law Number
1976	ERDDA	94-475
1977	ERDDA of 1978	95-155
1978	ERDDA of 1979	95-477
1979	ERDDA of 1980	96-229
1980	ERDDA of 1981	96-569

[1] See Appendix 1 for EPA organizational structure.

Since 1981, there have been a number of bills introduced to reauthorize ERDDA that were not ultimately enacted into law.[2] As a result, explicit authorization of EPA's environmental R&D ended at the end of fiscal year 1981. This failure to comprehensively reauthorize EPA research, development, and demonstration programs and activities illustrates a broader trend among expired environmental statutes. The Congressional Research Service notes this trend, stating, "Although Congress somewhat recently has renewed the authorization of appropriations for certain EPA programs and activities through targeted amendments to various statutes, a more comprehensive reauthorization of many of the statutes that EPA administers has not been enacted for a number of years."[3]

In addition to ERDDA, EPA also derives authority for R&D activities through other major environmental statutes. For example, under the Clean Air Act, the EPA Administrator must issue criteria that "accurately reflect the latest scientific knowledge useful in indicating the kind of extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air."[4] Through the Safe Drinking Water Act (SDWA), EPA sets standards based on "the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices."[5] Similarly, the Clean Water Act (CWA) requires EPA to publish water quality information "accurately reflecting the latest scientific knowledge."[6]

In many cases, these major regulatory statutes also authorize specific R&D programs and activities. For example, the Clear Air Act established a national research and development program for the prevention and control of air pollution including establishing technical advisory committees and research on air pollutant monitoring. The SDWA authorized the Administrator of EPA to conduct research and studies relating to the causes, diagnosis, treatment, control, and prevention of physical or mental diseases resulting directly or indirectly from contaminants in the water including improved methods to identify and measure contaminants in drinking water and improved methods to identify and measure the health effects of contaminants in drinking water. The CWA directed the Administrator to establish national programs for the prevention, reduction, and elimination of pollution and as part of such programs to work in cooperation with other State and federal agencies to coordinate and accelerate research, investigation, experiments, demonstrations, and studies relating to the causes, effects, extent, prevention, reduction, and elimination of pollution in the navigable waters of the U.S.

The science enterprise at EPA is spread across program offices and regions. ORD is organized into three national labs (comprised of 18 separate labs) and four national centers (which have 19 divisions).[7] In addition to 18 labs within ORD, there are nine labs split among several program offices and each of the 10 regions has its own lab.[8] In FY 2010, the appropriations level for EPA Science and Technology activities (S&T includes ORD and the other 19 labs) was $874.9 million. The appropriations level for FY 2011 was $840.3 million. The FY 2012 House Committee-passed appropriations level is $777.6 million, and the FY 2012 Senate Committee draft appropriations level is $809 million.

The fragmented nature of EPA R&D presents a challenge to program management and coordination and has complicated efforts to evaluate the effectiveness of these activities. Numerous studies conducted by the EPA Office of Inspector General, the Government Accountability Office, and others have cited significant concerns with the science activities of the Agency and the difficulties in evaluating the usefulness of the science to program needs. These studies have offered recommendations on how to improve the science enterprise at EPA, but many of these recommendations have not been implemented.

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[2] HR 3115 (1982), HR 2804 (1982), S. 1205 (1982), S. 2577 (1983), HR 2899 (1984), S. 1292 (1984), HR 2319 (1985), S. 2702 (1985), S. 1144 (1986), HR 2355 (1987), HR 1523 (1987), HR 2153 (1989), HR 4873 (1990), HR 2404 (1991), S. 1655 (1991), HR 1994 (1993), S. 1545 (1993), HR 2405 (1995), HR 1814 (1995), HR 3322 (1996), HR 1276 (1997), HR 1742 (1999), HR 1743 (1999).

[3] Congressional Research Service, "Environmental Laws: Summaries of Major Statutes Administered by the Environmental Protection Agency," RL30798, August 11, 2011.

[4] 42 U.S.C. §7408(a)(2) (2000).

[5] 42 U.S.C. §300g–1(b)(3)(A)(i).

[6] 33 U.S.C. §1314(a)(1).

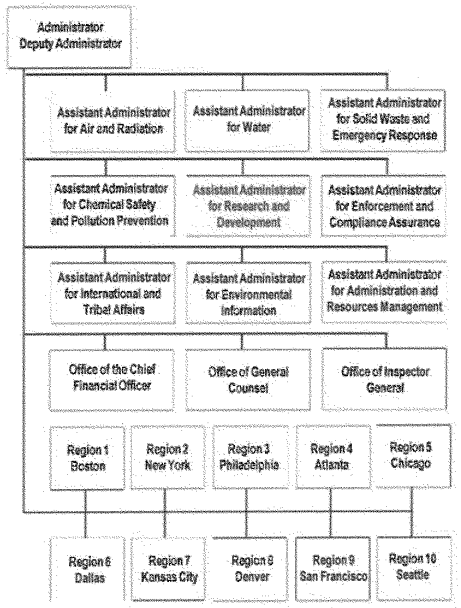
[7] See Appendix 2.

[8] See Appendix 3.

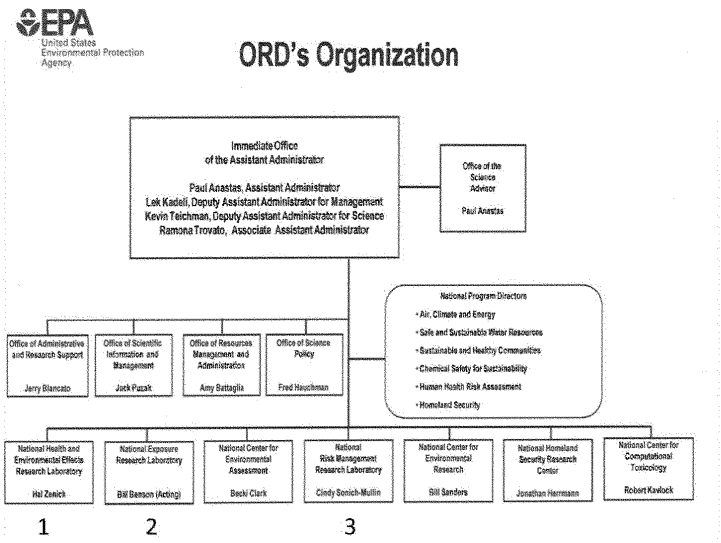
Appendix 1

EPA
United States Environmental Protection Agency

U.S. EPA Organizational Chart

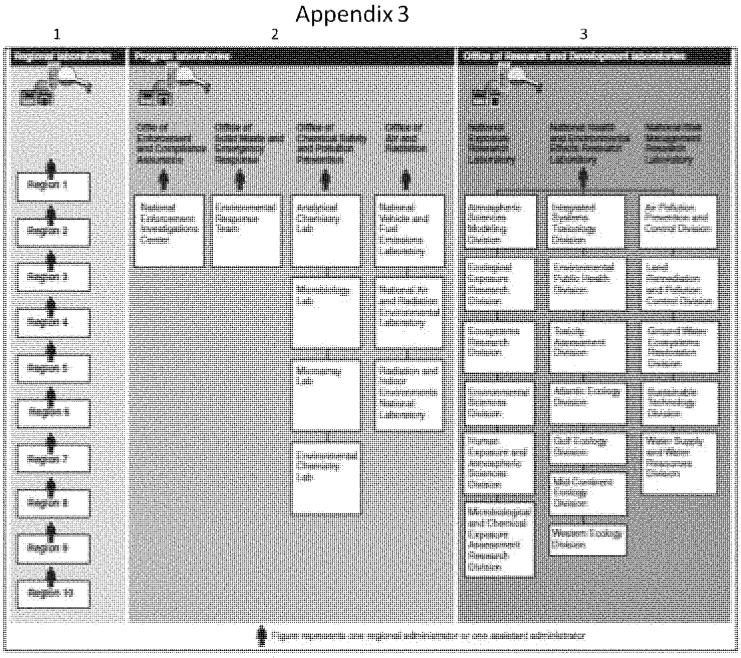


Appendix 2



The bottom of this chart shows three national labs and four national centers. The three national labs are broken down in Appendix 3.

Appendix 3



Column 1 shows 10 regional labs. Column 2 shows 9 program labs. Column 3 shows 18 ORD labs.

Chairman HARRIS. The Subcommittee on Energy and Environment will come to order.

Good morning. Welcome to day two of the hearing entitled "Fostering Quality Science at EPA: Perspectives on Common Sense Reform."

In front of you are packets containing the written testimony, biographies and Truth in Testimony disclosures for today's witness panel.

I want to welcome everyone, and we will have five minutes for opening statements by myself and the ranking member. I want to welcome everyone to the second day of our hearing on fostering quality science at EPA. As this is a continuation of the hearing held on November 30th of last year, I will be brief.

Unfortunately, the Environmental Research, Development, and Demonstration Authorization Act, or ERDDAA, which is the statute authorizing R&D at EPA as well as the Science Advisory Board, was last reauthorized for fiscal year 1981. I think we can all agree that our fiscal, environmental, and economic priorities have changed dramatically over the past 30 years, and we should have statutes and a Congressional role in environmental policy that reflects those changes. As we have held nearly a dozen oversight hearings on specific EPA issues during this Congress, we have seen patterns of behavior that suggest the need for significant reforms.

At day one of this hearing, we received testimony from several witnesses with decades of experience with the Agency: Susan Dudley of George Washington University, who formerly served as head of the White House Office of Information and Regulatory Affairs; Alan Moghissi of the Institute for Regulatory Science; Ken Green of the American Enterprise Institute; and Gary Marchant of Arizona State University. They provided specific recommendations on reforming scientific activities at EPA, including the need to separate science and policy; to quantify uncertainties; to ensure greater transparency in the data, models, and assumptions used in regulatory decisions; to prioritize environmental problems and solutions; and to stop overly alarmist approaches to benefit-cost analysis.

I want to thank the witnesses for appearing before the Subcommittee, and I look forward to continuing this important conversation with this panel of experts. That concludes my opening statement.

[The prepared statement of Mr. Harris follows:]

PREPARED STATEMENT OF CHAIRMAN ANDY HARRIS

I want to welcome everyone to the second day of our hearing on "Fostering Quality Science at EPA: Perspectives on Common Sense Reform."

As this is a continuation of the hearing held on November 30th of last year, I will be brief.

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I want to thank the witnesses for appearing before the Subcommittee, and I look forward to continuing this important conversation with this panel of experts.

Chairman HARRIS. Mr. Miller.

Mr. MILLER. Thank you, Chairman Harris.

Today the Subcommittee, as Chairman Harris said, meets again for part two of the hearing we held at the end of November on science at the EPA. The first two hearings in this series were a disappointment, and a missed opportunity to build a helpful record in preparation for the reauthorization of the Environmental Research, Development, and Demonstration Authorization Act. Mercifully, there is an acronym: ERDDAA.

However, today, I am pleased to see that we have some panelists with the experience and knowledge required to address in detail critical improvements that can make EPA's research enterprise more effective, efficient, and transparent. At the least, this is not just a panel of witnesses armed only with talking points and flailing criticism meant to undermine or dismantle the one agency charged with protecting our citizens and the environment from unlawful pollution. Let us use their time and ours wisely.

As I have said before, I approach this task hoping to work with my Republican counterparts in pursuing reforms that will lead to better research practices that help EPA accomplish its mission. While we will not always agree on the best way to do that, I am not interested in restructuring EPA to take the only environmental cop off the beat. There are legitimate concerns related to EPA's research infrastructure and processes, but they are complex, and we have to approach the process in a well-thought out and planned manner.

I have authored and co-authored many bills in my time here. I understand the amount of research, stakeholder conversations, and thought that must take place to write legislation as important and ambitious as the reauthorization of ERDDAA.

EPA's scientific research is increasingly important as we seek to understand and address more complex environmental issues that continue to emerge and evolve. That was demonstrated just 48 hours ago when this Subcommittee met to consider EPA's role in examining groundwater research and the start of the Pavillion Study process.

Scientific research knowledge and technical information are fundamental to EPA's mission, and to inform its standard-setting, regulatory, compliance, and enforcement functions. That is why Congress created advisory bodies such as the Clean Air Scientific Advisory Committee and the Science Advisory Board that were created to provide independent advice on the science that allows the Ad-

ministrator to make regulatory decisions. In addition to advice from an array of experts from many fields, the scientific process also involves the use of epidemiology and modeling to aid in hazard identification, which is only the first stage of quantitative risk assessment.

But in the scientific process, epidemiology and modeling investigations are not the only approach to research studies. It is a multidisciplinary approach that includes real-time monitoring, clinical and laboratory studies, model development, measurement and exposure methods, characterization of sources, and control technologies. Just like the process we need in reauthorizing ERDDAA, the responsibility of the scientific process and regulatory decision making takes a host of perspectives, methods, and techniques.

In short, science should inform and support the decisions we make, that Congress makes and the EPA makes, and most important, we all have an ultimate responsibility to do everything we can to make sure that everyone enjoys a decent quality of life.

And Chairman Harris, I yield back.

[The prepared statement of Mr. Miller follows:]

PREPARED STATEMENT OF RANKING MEMBER BRAD MILLER

Thank you, Chairman Harris. Today the Subcommittee meets again for part two of the hearing we held at the end of November on science at the EPA. The first two hearings in this series were a disappointment and a missed opportunity to build a helpful record in preparation for the reauthorization of the Environmental Research, Development, and Demonstration Authorization Act, or ERDDA.

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In short, science should inform and support the decisions we make. And most important, we all have an ultimate responsibility to do everything we can to ensure that EVERYONE continues to enjoy a decent quality of life.

With that, Chairman Harris, I yield back.

Chairman HARRIS. Thank you very much.

At this time I would like to introduce our witness panel and thank each of them for appearing before us today.

Our first witness is Mr. Daniel Greenbaum, President and CEO of the Health Effects Institute. He has been a member of the U.S. National Research Council, Board of Environmental Studies and Toxicology, and Vice Chair of its Committee for Air Quality Management. Mr. Greenbaum has over three decades of governmental and non-governmental experience in environmental health.

Our next witness is Dr. Deborah Swackhamer, a Professor of Environmental Health Sciences at the University of Minnesota and the Chairwoman of the EPA Science Advisory Board. She is also a Governor appointee on the Minnesota Clean Water Council and recently completed a one-year term as President of the National Institute of Water Resources. She is also a member of the Editorial Advisory Board for the Journal *Environmental Science and Technology* and is Chair of the Editorial Advisory Board of the *Journal of Environmental Monitoring* through the end of last year.

Our third witness is Mr. Michael Walls, Vice President of Regulatory and Technical Affairs for the American Chemistry Council. He has experience in a wide range of domestic chemical regulatory issues including the Toxic Substance Control Act, Emergency Planning and Community Right to Know Act, and the Resource Conservation and Recovery Act. His experience also includes work on international chemical regulatory issues, including the Europe Commission's Registration, Evaluation and Authorization of Chemicals.

Our fourth witness is Dr. Richard Belzer, President of Regulatory Checkbook. From 1988 to 1998, Dr. Belzer served as Staff Economist in OMB's Office of Information and Regulatory Affairs, where he reviewed major federal regulations and the supporting analyses. He focused primarily on the assessment of benefits and opportunity costs, both of which involve crucial links to human health risk assessments.

Our fifth witness is Dr. Jerald Schnoor, Allen S. Henry Chair in Engineering in the Department of Civil and Environmental Engineering at the University of Iowa. Dr. Schnoor chaired the Board of Scientific Counselors for the Environmental Protection Agency, Office of Research and Development, from 2000 to 2004. While serving as Editor in Chief of *Environmental Science and Technology*, he guided the leading journal in the world in both environmental engineering and environmental science.

Our sixth and final witness is Dr. S. Stanley Young, the Assistant Director for Bioinformatics at the National Institute of Statistical Sciences. He is a fellow of the American Statistical Association and the American Association for the Advancement of Science. He has authored or co-authored over 50 papers including six Best

Paper Awards and a highly cited book, *Resampling Based Multiple Testing*.

Thank you all for appearing before the Subcommittee today. As our witnesses should know, spoken testimony is limited to five minutes each, after which the Members of the Committee will have five minutes each to ask questions.

I now recognize our first witness, Mr. Daniel Greenbaum of the Health Effects Institute.

STATEMENT OF MR. DANIEL GREENBAUM,
PRESIDENT AND CHIEF EXECUTIVE OFFICER,
HEALTH EFFECTS INSTITUTE

Mr. GREENBAUM. Mr. Chairman and Members of the Committee, I am pleased to appear before you today. I am Dan Greenbaum, as you said, from the Health Effects Institute. We are a nonprofit research institute with joint and balanced funding from U.S. EPA and industry that for over 30 years has produced trusted science to inform air quality decisions. I draw on HEI's and other experiences to highlight five important principles for producing credible science.

HEI was born out of controversy between EPA and industry over whose science could be believed. We were established as an independent, nonpartisan entity to produce health science that could be agreed to by all parties, and we are designed with several key elements to ensure impartiality: an independent, high-level board of directors of distinguished science and policy leaders who are not from sponsors; standing committees of independent, respected experts; a research committee to oversee all research; and a separate review committee to conduct intensive peer review of all research and prepare a commentary on the findings. The board also appoints special expert committees to conduct targeted re-analyses of key studies and systematic reviews of the literature.

All results from HEI are published and available for free, and we work to actively provide access to all underlying data. And importantly, HEI produces policy-relevant science, but we do not take policy positions.

Now, HEI was not established to replace all science produced for air quality and other environmental decisions but HEI's design was designed to produce science of the highest quality and credibility in often controversial circumstances. Five key principles guide this work.

First, we engage scientists who are independent and objective, scientists from a wide variety of arenas, not just environment and health. It is essential that public and private science organizations actively reach out to the widest possible range of scientists with diverse perspectives and skills. Now, scientist recruitment must also avoid real or readily perceived conflicts of interest, and HEI, the National Academies, EPA and others have procedures in place to identify these, but these reviews of conflicts should not become a straitjacket that, for example, disqualifies well-qualified scientists just because they have been funded at times by industry or EPA

or an environmental organization. We need the best science, as long as it is objective, from wherever it can come.

Second, science should be funded through vigorous, open competition. HEI and a number of others including U.S. EPA's Star Grant program, which has received exemplary reviews from the National Research Council, use well-established techniques for soliciting, reviewing, scoring and selecting projects. Again, the broad-based recruitment of scientists to compete and participate in these processes is essential to ensuring a level playing field for the widest possible sets of institutes and science perspectives.

Third, we need to apply the full range of multidisciplinary skills, drawing on experts in emissions, exposure, toxicology and epidemiology, but perhaps most important, we at HEI have placed the field of statistics at the center of our work, insisting on predesigned statistical analysis plans and subjecting each study's results to detailed statistical review to make sure that the best techniques were applied.

Fourth, all results must be subjected to intense peer review and re-analysis if needed. Now, peer review has been a cornerstone of science for many years, but with the profusion of scientific journals in recent years, the quality of peer review can vary substantially. This is further complicated by the tendency of some journals to be more interested in publishing studies that have found a positive effect, or so-called publication bias. HEI's peer review process requires a comprehensive report of all findings, not only positive results, a broad-based standing expert peer review panel which has had nothing to do with the study, the active engagement of at least two statisticians in each review, and the ability to request and gain access to all underlying data as part of that review.

And finally, science should be conducted and reported with full transparency. HEI seeks to produce its work with the widest degree of disclosure of results and underlying data. This is critical to ensuring that all positive and negative results are reported and that the broader science community can access and further analyze the results and data. We have even placed entire databases for our studies on the Web for anybody to go to at any time when that was possible.

Thank you for this opportunity to testify. I would be pleased to answer any questions.

[The prepared statement of Mr. Greenbaum follows:]

PREPARED STATEMENT OF MR. DANIEL GREENBAUM,
PRESIDENT AND CHIEF EXECUTIVE OFFICER,
HEALTH EFFECTS INSTITUTE

Summary

The production of high-quality, credible science is of critical importance to informing often-controversial policy decisions on environment and health. For over 30 years, the Health Effects Institute, an independent, not-for-profit research institute with joint and balanced funding from U.S. EPA and industry, has produced trusted science in a variety of forms to inform air quality decisions. This testimony draws from that experience—and from the results of the recent report of the Bipartisan Policy Center (*Improving the Use of Science in Regulatory Policy*)—to highlight key principles of producing credible science, including:

- Engaging scientists who are *independent and objective*;

- Funding science through vigorous *open competition*;
- Applying the *full range of multi-disciplinary skills*;
- Subjecting all results to *intense peer review*, and *re-analysis* if needed; and
- Conducting and reporting science with *full transparency*.

This testimony describes how each of these key principles contributes to producing credible science; the critical elements necessary for applying them successfully, and the degree to which practice at US EPA and elsewhere in government includes these approaches currently and/or could be enhanced.

Testimony

Mr. Chairman, and Members of the Committee, it is my pleasure to appear before you at this important hearing, "Fostering Quality Science at EPA: Perspectives on Common Sense Reform—Day II." I am Daniel S. Greenbaum, President of the Health Effects Institute (HEI), an independent, not-for-profit research institute with joint and balanced funding from U.S. EPA and industry that, for over 30 years, has produced trusted science in a variety of forms to inform air quality decisions. I also was pleased to serve recently on the Committee of the Bipartisan Policy Center on Science and Policy, a multi-party expert panel that made recommendations [1] on improving the development and use of science in policy. I draw on the rich experience of HEI, and the recommendations of the Science and Policy Committee to highlight several important principles for producing credible science to inform environment and health decisions.

The Health Effects Institute

HEI was born out of controversy. During implementation of the Clean Air Act rules for air quality and vehicle emissions in the 1970s, there was substantial disagreement between manufacturers and the U.S. EPA about the underlying health science driving decisions. HEI was established with the support of U.S. EPA and industry as an independent, non-partisan entity to produce health science that could be agreed to by all parties—and could serve as the basis for better decisions. HEI is designed with several key elements to ensure its impartiality:

- *Joint and balanced core funding from US EPA and industry*;
- An *independent, high-level Board of Directors* of distinguished science and policy leaders to guarantee the integrity of the science, with members agreed to by the EPA Administrator and industry but not containing any current sponsor employees;
- Standing Committees of subject matter experts in exposure, toxicology, epidemiology, statistics and other disciplines who are not employees of sponsors and who may not have demonstrated "a lack of objectivity" in their field:
- *Research Committee* to design, conduct competitions for, and oversee all research;
- *Review Committee* to conduct intensive peer review of all HEI-funded research, and prepare a Commentary on the scientific findings and their implications for decisions.
- Special Expert Committees appointed according to the same principles to conduct targeted *reanalyses* of key studies and *systematic reviews of the literature* in important areas.
- Full *transparency*, with all results published and available for free electronically, and active provision of access to underlying data;
- Importantly, HEI produces policy-relevant science, *but does not take policy positions*.

With these elements in place, HEI has funded over 250 studies of a wide range of air pollutants; reanalyses of a number of epidemiologic studies central to decisions; and special reviews of the literature on diesel exhaust, air toxics, traffic effects, and more. HEI's work has been widely accepted as credible and comprehensive and is regularly cited in decision making in the U.S. and worldwide.

[1] Bipartisan Policy Center. 2009. Improving the Use of Science in Regulatory Policy. Washington, DC: Bipartisan Policy Center.

Principles of Credible Science

HEI was not established to replace all science produced for air quality policy decisions. Much science was then, and is today, produced directly with funding from U.S. EPA, the National Institutes of Health, and others. But HEI's design was developed to produce science of the highest quality and credibility at the most critical and often controversial junctures of science and decisions, and the key principles that HEI has applied can inform the enhancing of credibility of all science produced for informing decisions. These key principles are:

- Engaging scientists who are *independent and objective*: Quality science for decisions requires the active involvement of a wide range of talented individuals from diverse perspectives. Many scientists are fully engaged in their research and teaching and hesitant to become overly involved in often-controversial science/policy settings. One result of this is that at times one can find a range of scientists actively engaged in the work of organizations like the National Academy of Sciences, but despite the best recruitment efforts of entities such as the Science Advisory Board, unwilling to engage in the scientific work of agencies like EPA. To further enhance skills, HEI has sought to engage scientists from a wide variety of arenas, not just environment and health; it is essential that public and private science organizations actively reach out to the widest possible range of scientists, seeking consciously to engage scientists with diverse perspectives and skills.

  For maximum credibility, scientist recruitment must also ensure that scientists do not carry with them real or readily perceived conflicts of interest, e.g., a direct financial interest in the outcome of the scientific deliberation. The BPC Science and Policy Report systematically reviews the many detailed approaches that have been adopted by U.S. EPA, other federal agencies, the NAS, and others for identifying both biases and conflicts of interest, and recommends enhanced approaches to this important task.

It is important, however, that such reviews of bias and conflicts not act to unnecessarily place scientist selection in a "strait jacket" that, for example, disqualifies well-qualified scientists simply because they have been funded by industry or U.S. EPA, or have done work or work currently for industry or an environmental organization. Some of the best experts have received funds from a range of sponsors, are capable of providing a balanced perspective on the science, and should be included unless there is a real and current conflict of interest.

- Funding science through vigorous *open competition*: A hallmark of the highest-quality science is to ensure that it is selected and funded through the highest levels of peer-reviewed competition. HEI and a number of other research programs, including U.S. EPA's STAR grants program (which has received exemplary reviews from the National Research Council) have used well-established techniques for soliciting, reviewing, scoring, and selecting such projects. At the same time, this is an area where the broad-based recruitment of scientists to participate in these selection processes, and the recusal of scientists from reviewing applications from their own institutions, is essential to ensuring a "level playing field" for competitors from the widest possible set of institutions and scientific perspectives.
- Applying the *full range of multi-disciplinary skills*: Since its inception, HEI has seen fully multi-disciplinary science as the only way to answer complex questions facing decision makers in environmental health. Thus, for example, a team studying the health effects of certain emissions, or peer reviewing the results of such a study, must include engineering and exposure measurement expertise. And the best health studies will draw on a combination of toxicological and epidemiological techniques to determine whether a certain exposure is having an effect. Perhaps most important, HEI has placed the field of biostatistics at the center of its work, insisting on pre-designed statistical analysis plans for each major project, and subjecting each study's results to intense statistical review to ensure that (a) the best and most appropriate statistical techniques were applied and (b) any positive results (i.e., those showing an "effect") are placed in the context of the full range on positive and negative results before interpreting the study's conclusions.
- Subjecting all results to *intense peer review*, and *re-analysis* if needed: Peer review has been a cornerstone of science for generations and has served well, in general, to identify the strongest contributions to the scientific literature on a wide variety of topics. However, with the profusion of scientific journals in re-

cent years, and the diversification of peer review processes, the degree to which any particular journal article is subjected to the highest level of peer review can vary substantially. This is further complicated by the tendency of journals to be more interested in publishing studies that have found a positive "effect," a "publication bias" which has now been documented in a number of settings.[2]

The HEI peer review process was designed to address these shortcomings, especially for science at critical intersections between science and decisions. That process includes several key elements: (a) a comprehensive report of all findings, not necessarily only the "positive" results; (b) a broad-based standing panel of experts (the HEI Review Committee) which has had nothing to do with the study and meets in person to review each report and to prepare a detailed Commentary on the study findings and their implications; (c) the active engagement of at least two biostatisticians in each review; and (d) the contractual ability to request and gain access to all underlying data generated in the study and used in the analysis. These and other steps result in a level of peer review that is widely regarded as being as intense as, and in some cases more intense than, the peer review at the best scientific journals.

HEI has, at times, also been asked by Congress, U.S. EPA, industry, and others to go beyond its intensive peer review of its own studies to play two other intense review roles: the reanalysis of key studies that are particularly central to decisions (e.g., the HEI reanalysis of the Harvard Six Cities and American Cancer Society studies),[3] and the systematic review of the complete scientific literature on emissions, exposure, and health (e.g., recent reviews of the science on the potential effects of exposure to air toxics and to traffic-generated air pollution).[4] In each of these cases HEI's Board of Directors appoints multi-disciplinary expert panels according to the same principles of independence to oversee reanalysis and systematic literature reviews. And those efforts are then in turn subjected to high levels of peer review by experts who have not previously been involved.

- Conducting and reporting science with *full transparency*: From its inception, HEI has sought to produce its work with the widest degree of disclosure of results and underlying data. This is critical to ensuring that all results—both positive and negative—are reported, and that the broader science community can fully access, and further analyze, the results and data. HEI's comprehensive reports present, for free Web distribution, all methods and results, along with the Commentary of the HEI Review Committee. And since the mid-1990s, HEI's Board of Directors has had in place a Data Access Policy that has both encouraged HEI investigators to make their data and analysis freely available on the Web (for example, the data underlying HEI's National Morbidity, Mortality and Air Pollution Study (NMMAPS)),[5] and to facilitate—wherever HEI investigators have full ownership of underlying data—access for other investigators to the data.

Conclusions—Toward Credible Science for Environment and Health Decisions

In conclusion, it is clear that science can and should play an important role in providing the foundation for decisions on environment and health, and that to do so, the science needs to be of the highest quality and credibility. U.S. EPA and other agencies have established procedures to produce and review science for decisions, and in many cases those procedures work to enhance the quality and credibility of the science. The HEI experience, founded out of a desire by both industry and U.S. EPA for more readily trusted science, has illustrated a number of key principles that can lead to even better science for decisions in the years to come. Thank you

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[2] Cf. Samet J.M., Zeger S.L., Dominici F., Curriero F., Coursac I., Dockery D.W., Schwartz J., Zanobetti A. 2000. The National Morbidity, Mortality, and Air Pollution Study, Part II: Morbidity and Mortality from Air Pollution in the United States. Research Report 94. Health Effects Institute, Cambridge, MA.

[3] Krewski D., Burnett R.T., Goldberg M.S., Hoover K., Siemiatycki J., Jerrett M., Abrahamowicz M., White W.H. 2000. Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality. A Special Report of the Institute's Particle Epidemiology Reanalysis Project. Health Effects Institute, Cambridge, MA.

[4] Cf. HEI Panel on the Health Effects of Traffic-Related Air Pollution. 2010. Traffic-Related Air Pollution: A Critical Review of the Literature on Emissions, Exposure, and Health Effects. HEI Special Report 17. Health Effects Institute, Boston, MA.

[5] *www.ihapss.jhsph.edu*.

for this opportunity to testify. I would be pleased to answer any questions the Committee may have.

Chairman HARRIS. Thank you very much.

I now recognize our second witness, Dr. Deborah Swackhamer of the University of Minnesota and Chairwoman of the EPA Science Advisory Board.

STATEMENT OF DR. DEBORAH SWACKHAMER, PROFESSOR, ENVIRONMENTAL HEALTH SCIENCES, UNIVERSITY OF MINNESOTA, AND CHAIRWOMAN, EPA SCIENCE ADVISORY BOARD

Dr. SWACKHAMMER. Good morning, Chairman Harris, Ranking Member Miller and distinguished Committee Members. My name is Deborah Swackhamer, and I hold the Denny Chair in Science Technology and Public Policy at the Humphrey School of Public Affairs at the University of Minnesota. I am trained as an environmental chemist, and I am Professor of Environmental Health Sciences in the School of Public Health and co-direct the University's Water Resources Center.

I was appointed Chair of the SAB in 2008 by EPA Administrator Stephen Johnson and reappointed for a second term in 2010 by Administrator Lisa Jackson. While my perspectives and opinions are my own, I am testifying today on behalf of the SAB.

The SAB provides science advice to the EPA Administrator on a wide range of scientific and technical issues. These issues are complex, and they require a diversity of experience to address. The SAB membership brings expert knowledge from the natural and physical sciences, engineering, health sciences, and social sciences including economics. Based on my years of service on the board, I believe that the agency has a robust process for identifying members with outstanding scientific credentials who are committed to helping improve the quality of agency science. The SAB and its committees and panels review agency work products, undertake special studies when requested, and perform self-initiated studies on topics that the Board considers to be of critical importance.

Recent SAB advice that is directly relevant to this hearing includes two reports we produced in 2009 and 2010 on strategic directions for EPA research prepared for ORD to encourage approaches and strategies needed to do their science most effectively. These two reports have been instrumental in moving ORD's research enterprise towards a more interdisciplinary approach and one that can respond more nimbly and effectively to the needs of the program offices and the regional offices. The Administrator's One EPA and ORD Assistant Administrator Anastas's "The Path Forward" strategies are consistent with our previous advice. The board is in the process of finalizing a report on how the agency can do a better job of integrating science and problem formulation in its decision making.

The SAB is supportive of many changes that have taken place in ORD in recent years. More could be done, more is being done, but I believe and our reports have indicated that ORD is moving in the right direction. We have advised strongly for an integrated approach to EPA's scientific research, and the agency has responded, as indicated by the realignment of research programs

from 13 independent programs to six integrated programs. We have advised to include a greater degree of social and decision science research, and the agency is moving to fill this need. We have advised to develop the capacity to respond to emerging issues and the new program structure should move them in the right direction. We have advised the agency to partner more nationally and internationally and develop truly collaborative research efforts in these times of limited and shrinking resources, and they have been creative in doing so. Finally, we urged ORD to support and creative incentives for their scientists to be more innovative, and they have responded.

The SAB and presumably this Subcommittee share the goal and commitment to assist EPA in producing and using high-quality science to protect human health and the environment. The best available science is essential to sound decision making but is not the only aspect of sound policy decisions. What is best available science? While hard to provide a simple one-size-fits-all definition, generally, it is scientific results, conclusions, and technical information that has been produced using proven methods that has been peer reviewed where hypotheses are tested with objective and unbiased approaches and that has the support for its conclusions from other independent studies. The role of the SAB is to examine the scientific and technical knowledge that was synthesized within the agency on a given issue and provide advice as to whether this science was appropriate and adequate for its intended use.

Finally, the letter from Chairman Harris requested that I comment on the capability of EPA to conduct and use the best available science to fulfill its mission. The agency certainly has the capability, given its excellent scientific enterprise. It is sorely short of resources to provide the capacity needed for all the science questions at the agency, and yet, there is no other agency where such environmentally focused and directed science is being done to fill the unique mission of protecting the public's health and the environment on which they depend.

Investing in EPA science is a wise investment. That said, this capability would be improved by continuing to address scientific questions from an interdisciplinary approach, by partnering more creatively with others, by involving stakeholders in problem formulation, and integrating science across the agency for the most effective decision making.

Thank you for the opportunity to speak with you today.

[The prepared statement of Dr. Swackhamer follows:]

PREPARED STATEMENT OF DR. DEBORAH SWACKHAMER, PROFESSOR, ENVIRONMENTAL HEALTH SCIENCES, UNIVERSITY OF MINNESOTA, AND CHAIRWOMAN, EPA SCIENCE ADVISORY BOARD

My name is Deborah Swackhamer, and I hold the Charles M. Denny, Jr., Chair in Science, Technology, and Public Policy in the Hubert H. Humphrey School of Public Affairs at the University of Minnesota, and co-direct the University's Water Resources Center. I am trained as an environmental chemist and am also professor of Environmental Health Sciences in the School of Public Health.

I was appointed chair of the SAB in 2008 by EPA Administrator Stephen Johnson and reappointed for a second term in 2010 by EPA Administrator Lisa Jackson. From 2006–2008, I served on the Board of Scientific Counselors (BOSC) for EPA's Office of Research and Development (ORD). While my views, perspectives, and opinions are my own, I am testifying at this hearing on behalf of the SAB.

The Role of the SAB

The SAB provides science advice to the EPA Administrator on a wide range of scientific and technical issues. These issues are complex and require a diversity of expertise to address. The SAB membership brings expert knowledge from the natural and physical sciences, engineering, health sciences, and social sciences including economics. Based on my years of service on the Board, I believe that the Agency has a robust process for identifying members with outstanding scientific credentials who are committed to helping improve the quality of Agency science. The SAB and its committees and panels review Agency work products, undertake special studies when requested, and perform self-initiated studies on topics that the Board considers to be of critical importance. The Board is in the process of finalizing a report on how the Agency can do a better job of integrating science and problem formulation in its decision making. [1]

Recent SAB advice that is directly relevant to this hearing includes the two reports we produced (2009, 2010) [2] on Strategic Directions for EPA Research, prepared for ORD to encourage approaches and strategies needed to do their science most effectively. These two reports have been instrumental in moving ORD's research enterprise towards a more interdisciplinary approach, and one that can respond more nimbly and effectively to the needs of the Program Offices and Regional Offices. The Administrator's "One EPA" and ORD Assistant Administrator Anastas' "The Path Forward" strategies are consistent with our previous advice.1A[3]

The SAB is supportive of many changes that have taken place in ORD in recent years. We have advised strongly for an integrated approach to EPA's scientific research, and the Agency has responded, as indicated by its realignment of research programs from 13 individual programs to six integrated programs. We have advised to include a greater degree of social and decision science research, and the Agency is moving to fill this need. The social sciences are a needed component to adequately address issues such as sustainability, homeland security, risk communication, valuation, and environmental stewardship and human behavior. The Agency needs to develop a strategy for developing this capability. We have advised to develop capacity to respond to emerging issues, and the new program structure should move them in that direction. We have advised the Agency to partner more nationally and internationally and develop truly collaborative research efforts in these times of limited and shrinking resources, and they have been creative in doing so. Finally, we urged ORD to support and create incentives for their scientists to be more innovative, and they have created a highly successful internal program for Innovation Grants and have modified their internal rewards system to encourage the best scientific publications.

To summarize, we are supportive of these changes at ORD. More could be done, more is being done, but I believe, and our reports have indicated, that ORD is moving in the right direction.

Quality, Usefulness and Objectivity of EPA Science—the Role of SAB

The SAB, and presumably this Subcommittee, share the goal and commitment to assist EPA in producing and using high-quality science to protect human health and the environment. The best available science is essential to sound decision making but is not the only aspect to sound policy decisions. What is "best available science"? While hard to provide a simple one-size-fits-all definition, generally it is scientific results, conclusions, and technical information that has been produced using proven methods, that has been peer reviewed, where hypotheses are tested with objective and unbiased approaches, and that has support for its conclusions from other independent studies. EPA cannot possibly do all of the science needed by the Program Offices and Regional Offices. Some of this needed science is conducted within EPA, and some science is used from outside research to verify, supplement, and in general add to the collective body of knowledge used to inform a given decision.

The role of the SAB is to examine the scientific and technical knowledge that was synthesized within the Agency for a given issue, and provide advice as to whether this science was appropriate and adequate for its intended use. In SAB reviews of EPA science assessments, we consider whether the data, reports, and other resources used were peer reviewed and compared and contrasted appropriately. It is

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[1] *Science Integration for Decision Making at the U.S. Environmental Protection Agency (EPA)* (draft January 5, 2012).

[2] *EPA's Strategic Research Directions 2008: An Advisory by the EPA Science Advisory Board*. EPA-SAB-09-006.

[3] *Office of Research and Development Strategic Research Directions and Integrated Transdisciplinary Research*. EPA-SAB-10-010.

my understanding that EPA has clear guidance regarding peer review of its own scientific work, and for data quality and transparency.[4] For purposes of maximum transparency and quality assurance, we usually advise the Agency not to include reports that have not been peer reviewed, or journal manuscripts in preparation or draft form but not yet published.

As a researcher who has received funding from EPA and many other agencies, I have found that EPA has very high standards for data quality and assurance.

Enhancing EPA Science

Finally, the letter from Chairman Harris requested that I comment on the capability of EPA to conduct and use the best available science to fulfill its mission. The Agency certainly has the capability given its excellent scientific enterprise. It is sorely short of resources to provide the capacity needed for all the science questions at the Agency, and yet there is no other agency where such environmentally focused and directed science is being done to fill the unique mission of protecting the public's health and the environment on which they depend. Investing in EPA science is a wise investment. That said, this capability would be improved by continuing to address scientific questions from an interdisciplinary approach, by partnering more creatively with others, by involving stakeholders in problem formulation, and integrating science across the Agency for the most effective decision making.

Thank you for the opportunity to speak to you today.

Chairman HARRIS. Thank you very much.

I now recognize our third witness, Mr. Michael Walls of the American Chemistry Council.

STATEMENT OF MR. MICHAEL WALLS,
VICE PRESIDENT, REGULATORY AND TECHNICAL AFFAIRS,
AMERICAN CHEMISTRY COUNCIL

Mr. WALLS. Good morning, and thank you very much for the opportunity to provide this testimony on behalf of the American Chemistry Council.

Now, the business of chemistry is fundamentally the business of science. The chemical industry practices high-quality science to foster the discovery of new chemistries and the development of new tools by which we can assess the hazards, uses, and exposures of chemicals. We similarly expect high-quality science and reliable assessment procedures to underpin effective and efficient regulatory decisions by the government.

Now, my testimony today boils down to a very simple message: the process for bringing science to bear in regulatory and policy decision making at EPA and at other federal agencies is broken. The quality of the science has suffered as a result, and the credibility and reliability of the decisions made on the basis of that science is at stake. Now, Congress, the agencies, the industry and the American public have a significant interest in using the best science to ground those decisions. The fact is that science and the government are reasonably likely to lead the regulatory decisions, and those decisions have practical implications for businesses, State, and local governments and individuals.

I would just like to focus on several examples drawn from EPA's IRIS program as well as some other government programs. The IRIS draft assessment on n-Butanol relies on two studies determined to be unreliable by the Organization for Economic Coopera-

[4] *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*. EPA/260R-02-008.

tion and Development in a review that was sponsored by yet another office within EPA. There is no indication that that conflict is going to be resolved. The National Academy of Sciences directed EPA to do nonlinear modeling in support of its IRIS assessment of dioxin. Five years later, EPA published yet another draft of the assessment that similarly failed to do the nonlinear modeling that was requested. EPA Science Advisory Board justly criticized the draft for that failure. The National Toxicology Program, part of the Department of Health and Human Services, issued its 12th report on carcinogens in July 2011. The report makes many of the same errors in its assessment of formaldehyde that the National Academy criticized EPA for in its own review of formaldehyde. That 12th report also viewed styrene and came to a sharply different conclusion than a 2010 evaluation by another division within HHS.

Why do we need to get this right? Well, in the IRIS case, it is particularly important because 80 percent of IRIS assessments haven't been updated in more than 15 years. Ninety percent are at least ten years old. Meanwhile, the science that informs our understanding of chemicals and of exposures has continued to advance by leaps and bounds. That new science should surely inform our regulatory and policy decisions.

The Federal Government's processes for assessing risk lack a consistent, coherent framework. That framework should bind the agencies to an appropriate and transparent approach to weigh the evidence, consider uncertainty, and keep up with advances in the field. Peer review is a critical step to ensure a high level of quality and reliability. Despite recommendations from the NAS and from the SAB, little has been done to ensure that peer review is consistent within and among the federal agencies. In short, we need to modernize and streamline these processes to meet both today's needs and our future challenges.

My written testimony outlines some recommendations for improving the quality and process of science in three areas. Number one, establishing sound risk assessment procedures, standards and criteria; two, enhancing peer review; and three, leveraging the emerging science and technology to reach better decisions.

The chemical industry looks forward to working with this Subcommittee in its continuing effort to improve science and risk assessment in the government. I very much appreciate the invitation to join the discussion today and look forward to your questions.

[The prepared statement of Mr. Walls follows:]

PREPARED STATEMENT OF MR. MICHAEL WALLS,
VICE PRESIDENT, REGULATORY AND TECHNICAL AFFAIRS,
AMERICAN CHEMISTRY COUNCIL

Summary

The American Chemistry Council (ACC) [1] very much appreciates this opportunity to provide testimony on common-sense measures to foster quality science at the Environmental Protection Agency (EPA) and throughout the Federal Government.

[1] The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier, and safer. ACC is committed to improved

Continued

The business of chemistry is fundamentally the business of science. This business of science is a critical component for manufacturing safe products required to house, feed, and protect people in the United States as well as provide for the tremendous quality of life experienced by American citizens who enjoy many high-quality and safe consumer goods that were unavailable just a few decades earlier. ACC member companies rely on science to conduct the research necessary to discover new chemistries and identify new applications of existing chemistries. They also rely on science to develop new tools for assessing the potential hazards, exposures, and risks of chemical substances. As one of the Nation's most regulated industries, ACC member companies similarly expect high-quality science—and reliable assessment processes—to underpin effective and efficient regulatory decisions by the Federal Government.

Unfortunately, processes for conducting and reviewing chemical assessments at EPA and other government agencies are not always based on the consistent use of the best available science. The lack of scientific quality and reliability directly compromises societal access to cost-effective and safe products that house, feed, and protect us while making life more enjoyable at the same time. While there has been much recent focus on EPA's Integrated Risk Information System (IRIS), the problems identified by the National Academy of Sciences (NAS) in the IRIS program are also evident in other government chemical assessment programs.

EPA has acknowledged many of the deficiencies in the IRIS program and is taking some welcome steps to address the concerns identified by the NAS. EPA is also making an important effort to develop and evaluate emerging technologies to improve chemical assessments, and ACC has been pleased to support these efforts.

ACC's testimony today outlines a number of recommendations to improve the quality and process of science at EPA and more broadly through the Federal Government. The following areas should receive particular attention:

- Improving the quality of science through sound risk assessment processes, standards and criteria.
- Improving the quality of science through enhanced peer review.
- Enhancing the quality of science by leveraging emerging science and technology.

I. Improving the Quality of Science Through Sound Risk Assessment Processes, Standards, and Criteria

The Subcommittee's inquiry into the level, quality, usefulness, and objectivity of science at the Environmental Protection Agency (EPA) is timely. There are well-known deficiencies in EPA's Integrated Risk Information System (IRIS)—deficiencies that Congress has directed the National Academy of Sciences to review. But the problems that affect the Agency's ability to assure that the science generated, reviewed, and used is of the highest quality are not unique to EPA.[2] ACC's testimony today outlines a number of recommendations to improve the quality and process of science at EPA and more broadly through the Federal Government.

At the heart of the problem in the Federal Government's processes for assessing risks to environment and human health is the lack of a consistent, coherent, science-based framework that binds the agencies to an appropriate and transparent approach for weighing evidence, considering uncertainty, and keeping up with advances in the field. The processes for considering scientific information and data and

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environmental, health, and safety performance through Responsible Carer, common-sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a $674 billion enterprise and a key element of the Nation's economy. It is one of the Nation's largest exporters, accounting for 10 cents out of every dollar in U.S. exports. Chemistry companies are among the largest investors in research and development. It is also one of the Nation's most heavily regulated industries.

[2] EPA's Integrated Risk Information System (IRIS) has been the focus of much critical attention recently. As the Subcommittee is well aware, the National Academy of Sciences (NAS) has expressed concern over "[t]he persistence of limitations of the IRIS assessment methods and reports, particularly in light of the continued evolution of risk-assessment methods and the growing societal and legislative pressure to evaluate many more chemicals in an expedient manner." The NAS report further cites a lack of clarity and transparency as a "repeating theme" over the last decade, insufficient documentation on methods and criteria for identifying evidence from relevant studies, and a lack of information useful in assessing the weight of the evidence, among other problems. These concerns are not limited to IRIS, or even EPA. For example, the Report on Carcinogens (RoC) issued by National Toxicology Program (NTP), housed in the Department of Health and Human Services (HHS). The 12th RoC, released in July 2011, makes many of the same methodological errors in its evaluation of formaldehyde as IRIS did in its review, and the 12th RoC's review of styrene conflicts with a 2010 evaluation by another HHS entity. Similar concerns exist with EPA's Clean Air Scientific Advisory Committee.

the standards and criteria used in risk assessment need to be modernized and streamlined to meet both today's needs and greater challenges of the future.

A. Integrated Risk Information System (IRIS)

Despite continued evolution of the EPA IRIS process, specific fundamental improvements to the program are necessary to ensure that IRIS assessments developed by EPA are firmly based on up-to-date scientific knowledge, meet the highest standards of scientific inquiry and integrity, and are evaluated in accordance with acceptable scientific approaches.

IRIS is used by EPA as the primary source of information regarding the potential adverse human health effects of chemicals. IRIS is also a leading source of health risk information for other federal, State, and international regulatory bodies. Given the importance that IRIS evaluations have for EPA program offices, other federal agencies, and State governments, as well as their impacts on the private and public sectors, it is clear that significant improvements are warranted and long overdue.

Many of these necessary improvements were outlined in Chapter 7 of the April 2011 NAS scientific peer review report on formaldehyde and underscored during two recent Congressional oversight hearings on IRIS. Despite general agreement with the need to make the changes recommended by the NAS, EPA has yet to provide further details on how it will implement the NAS IRIS improvements. The U.S. Government Accountability Office (GAO) has called on EPA to develop a clear plan for fixing IRIS. [3]

In an effort to move EPA in this direction, Congress recently passed bipartisan legislation which directs EPA in FY 2012 to:

- Incorporate, as appropriate, the recommendations of Chapter 7 of the National Research Council's Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde into the IRIS Process; and
- Issue a progress report to House and Senate Committees on Appropriations and relevant Congressional authorizing committees no later than March 1, 2012, describing its implementation of the National Research Council's Chapter 7 recommendations for ongoing and new assessments.

This action by Congress rightfully underscores the widespread agreement that more work is needed to improve IRIS so the program delivers scientifically defensible assessments.

EPA does not need to go back to square one to improve IRIS and the assessments already underway. But more than a cursory review and more than simple improvements are needed. In particular, EPA should determine whether all ongoing assessments—including those that the Agency is revising to take into account peer review and public comments—meet the NAS standards for reviewing studies, evaluating weight of evidence, determining mode of action, establishing cause and effect, and for selecting the dose-response method for quantifying potential health risks. If an IRIS assessment falls short, it must be upgraded.

ACC firmly believes that this process can be accomplished without undue delay in making IRIS assessments final. All stakeholders have an interest in IRIS assessments that rely on the best available scientific information regarding hazard and exposure; employ consistent, objective methods and models; utilize transparent evaluation procedures for data quality, cause and effect; and that weigh the full body of scientific evidence. If an ongoing IRIS assessment does not meet these criteria (for example, if a draft IRIS assessment does not employ a robust weight-of-the-evidence approach), the program must accept that more time will be needed to get the assessment right. The credibility of the IRIS program is not enhanced by assessments that fail to address the basic criteria for quality and reliability.

Importantly, there is nothing in the current IRIS program that provides an incentive for companies to develop new data and information and to use new toxicological methods and tools to generate and gather that data. Indeed, the industry has little confidence that new informationand data can overcome the conservative default assumptions employed in the program or the persistent problems identified in peer review.

In ACC's view, two principal solutions can help meet the Federal Government's need to enhance chemical risk assessment, and to restore credibility in the results. First, federal agency standards for risk assessment need to be updated. Ideally, the same set of updated standards would apply across the Federal Government. There

[3] Government Accountability Office, "Chemical Assessments: Challenges Remain With EPA's Integrated Risk Information System Program," GAO-12-42, Dec 9, 2011. Available at *http://www.gao.gov/assets/590/586620.pdf*.

are a variety of ways this might be accomplished. Second, the laws and rules governing scientific peer reviews should be updated to make that vital process more effective and transparent.

B. Improved Standards for Risk Assessment

Under existing authority, there is a clear role for the Office of Management and Budget (OMB) in reviewing agency assessments and coordinating a robust interagency review to promote uniformity in process and results. It is clear that federal risk assessment activities are not being coordinated, despite direction and guidance provided by OMB bulletins and memoranda.[4] Moreover, there is no current governmentwide oversight to ensure coordination. As a consequence, the lack of a coordinated approach to these various assessment programs creates the potential for duplication and inconsistent findings. Most troubling, each federal agency conducting such assessments does so in a different way, using different processes and standards.

To address this lack of coordination and consistency, federal agencies need to adopt updated state-of-the-art standards for human health and environmental risk assessments. Ideally, agencies would all follow a consistent set of standards. Agencies should be required to explain how they followed these standards, including providing a clear articulation of reasons for choices they made in the process. Agency compliance with those requirements would be enhanced if it were subject to regular oversight, including judicial review.

Federal standards for risk assessment should:

- Include criteria for evaluating the validity of test methods and the reliability and credibility of data.
- Require an assessment of the weight of evidence regarding hazard and exposure, based on criteria that should include elements such as a systematic review of all relevant and reliable toxicological, epidemiological, and mechanistic data, including negative results; a preference for human data, where it is relevant and adequate; and consideration of biologically plausible modes of action most relevant to humans.
- Require agencies to present the distribution of estimated hazards or risks, including central tendency values.
- Require agencies to characterize uncertainty and variability quantitatively, where feasible, and to explain these and other limitations of the analysis with sufficient clarity to be understood by non-scientists.
- Require full disclosure of:
- Data, methods and models sufficient to allow independent reanalysis by qualified experts;
- Rationales for choosing key studies, methods and models;
- Assumptions, extrapolations and policy judgments;
- Plausible alternatives and related impacts; and
- Major risk conclusions and degree of confidence based on uncertainties.
- Outline a process of stakeholder engagement, including:
- An interactive "problem formulation" at the outset of each assessment to identify key issues and data needs;
- Timing assessments to make maximum use of relevant external research; and
- Outreach regarding proposed charge questions for peer review of the assessment.
- Consider how the concept of proportionality can be addressed in risk assessment standards, so that risk assessments are more closely linked to the decision they are used to justify.

There are a number of options by which these standards can be developed and appropriate oversight of Agency adherence to the standards established.[5] For example, if the Environmental Research, Development, and Demonstration Authorization

[4] OMB "Final Information Quality Bulletin for Peer Review" and OMB's "Updated Principles for Risk Analysis" (*http://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2005/m05-03.pdf; http://www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/m07-24.pdf*).

[5] These proposals do not address who is responsible for generating the data that is used in these assessments. ACC assumes that companies will typically have that responsibility.

Act (ERDDA) is reauthorized, Congress can direct EPA to develop and implement these standards.

Congress could also consider a mandate that federal agencies collaborate in an interagency committee that would be tasked with developing risk assessment standards that all agencies would have to follow. This might include standards outlining the basic assumptions underlying risk assessment methodologies (such as concepts of threshold versus linear modeling), the use of animal data, and weight of the evidence approaches. The logic behind this approach is that it could bring together the agencies charged with balancing competing risks and benefits from protective interventions (e.g., the Food and Drug Administration, the Centers for Disease Control) with those agencies whose mandates are to reduce risks (e.g., EPA and the National Toxicology Program). The critical point, of course, is to avoid the development of lowest common denominator standards that simply preserve the status quo.

Congress could also direct the practice of federal agency risk assessment across the Federal Government by requiring the Office of Management and Budget (OMB) and the Office of Science and Technology Policy (OSTP) to develop standards broadly applicable across the government. Both OMB and OSTP have career staff knowledgeable about risk assessment and are interested in improving agency estimates of risks. In 2006, OMB and OSTP issued a proposed bulletin providing guidance to federal agencies regarding their conduct of health, safety, and environmental assessments.[6] Ultimately, OMB reinforced existing guidance, and noted an expectation that agencies would follow the principles. Unfortunately, agencies appear to routinely ignore these principles. Upper- and lower-bound estimates are not provided, negative studies are not discussed, and the uncertainties and limitations of the assessment are not articulated. Congress should ensure that agencies follow these basic principles.

II. Improving the Quality of Science Through Enhanced Peer Review

Integrating scientific methods across EPA and the federal agencies also requires enhancing the manner in which the broader scientific community is engaged in the assessment process. In ACC's view, the standards governing scientific peer reviews should be updated to make this vital process more effective. Peer engagement and review are two critical factors in the effort to ensure high-quality, reliable science supports decision making. Although ACC focuses on EPA in this section, the recommendations we provide should inform enhanced peer review across the government.

Independent peer review is a critical element of EPA's scientific policies and practices, and to date has received less attention than other elements of IRIS. Peer review is defined by EPA as "an in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to the specific major scientific and/or technical work product and of the documentation that supports them."[7] Peer review plays a crucial role in development of the best scientific evaluation and is integral to identifying information that would reduce uncertainty in significant areas of the assessment. The process of peer review should be structured to accomplish these objectives. There are several areas to consider for enhancing EPA's peer review process:

- Peer review panels need to have sufficient time and resources to fulfill their responsibilities.
- Rather than base peer review charge questions solely on the input provided by the lead agency office, the preparation of these charge questions should reflect stakeholder input and be developed using an iterative process. Development of the charge questions should be initiated at the problem formulation step, and then issued as a refined draft coinciding with the release of the draft IRIS assessment. Public comments on the draft charge questions should be solicited.
- Peer review charge questions should be written in order to facilitate objective consideration of alternative plausible scientific views rather than from the vantage point of giving deference to the interpretation presented in the Agency assessment. This provides peer reviewers greater opportunity to consider alternative scientific views such as those offered by stakeholders.
- As recommended in the Bipartisan Policy Center's report "Improving the Use of Science in Regulatory Policy," EPA should "explicitly differentiate between

[6] See 71 Fed. Reg. 2600 (Jan. 17, 2006).

[7] U.S. Environmental Protection Agency, Peer Review Handbook 3rd Edition, EPA/100/B-06/002, at 12. Available at *http://www.epa.gov/peerreview/pdfs/peer_review_handbook_2006.pdf*.

questions that involve scientific judgments and questions that involve judgments about economics, ethics and other matters of policy."[8]

- Peer review meetings should be structured to encourage open scientific dialogue and thoughtful scientific deliberation. Stakeholder input should not be limited to a few minutes at the beginning of a meeting; greater effort should be made to structure the meetings so that stakeholder input is provided and deliberated at strategic times throughout the meeting. Moreover, peer reviewers should not be dissuaded from embarking on open technical discussion/ scientific exchange with stakeholders.
- In selecting peer review panel members, the foremost consideration should be given to expertise. Qualified scientists from industry should be given equal consideration for appointment based on the subject matter, and in accordance with applicable conflict-of-interest provisions. There is unanimity among the most authoritative sources on this point, including the National Academies of Science and the Society of Toxicology:

  Appointments to scientific advisory bodies should be based principally on the scientific credentials, demonstrated accomplishments, and professional credibility of the nominee. His/her source of employment and funding (past or present), religious beliefs, political persuasion, sexual orientation, gender, or race/ethnicity should not be used as (a) determinant(s) of exclusion to such a scientific advisory body.[9]

The Office of Government Ethics (OGE) has issued detailed rules under the Ethics in Government Act (EGA) and the federal criminal code addressing conflict of interest, and impartiality, on the part of government employees, including "Special Government Employees" serving part-time on peer review committees. Fairly interpreted, the EGA and those rules strike a fair balance and allow persons employed by industry or non-governmental organizations to serve as reviewers in many cases. However, agencies have tended to interpret these rules in ways that (i) restrict the participation of industry personnel and (ii) are too accepting of persons who are not really independent of the agency or the work being reviewed. Congress may wish to revisit the EGA and the rules, and their role in promoting high-quality, reliable science.

In ACC's view, EPA's Science Advisory Board (SAB) has adopted generally sound processes and criteria for peer review of Agency action. There is room for improvement, however. For example, the SAB should ensure that the SAB peer reviewers fully understand their independent roles as peer reviewers. At times, however, it appears that peer reviewers are overly deferential to EPA, reluctant to be seen as criticizing EPA staff. It also appears that EPA staff have an unfettered ability to comment throughout the peer review meetings, and their constant presence may have a chilling effect on frank and open discussion among the peer reviewers. This practice contrasts sharply with NAS peer reviews.

ACC is generally encouraged by EPA's recent announcement that it will establish a standing SAB panel for IRIS assessments. Assuming that that standing panel is truly independent, and the panel process addresses the concerns such as the role of EPA staff and how review comments are incorporated into completed IRIS assessments, this approach could help promote a more reliable and consistent IRIS process.

Responding to peer review and public comments is another area where the Agency needs to make improvements in its practices. It is imperative that the Agency provide a robust response in writing to comments as part of the assessment revision process that follows the publiccomment and peer review phases. Where the Agency elects not to address a peer review finding or recommendation, or a significant public comment, EPA should provide a written justification. This practice should be made routine for all federal agencies.

The current practice of having the same office that develops the assessment draft the charge questions, review public and peer review comments, decide which recommendations and findings to act on and which to ignore, and develop the final assessment is clearly not a best practice. The inherent value of peer review—indeed the inherent value of EPA's SAB—is to provide an objective, robust scientific review of the agency's scientific work product. ACC believes there is value in having an "honest broker" to oversee and ensure that the Agency adequately revises assess-

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[8] The Center's report is available at *http://www.bipartisanpolicy.org/sites/default/files/BPC%20Science%20Report%20fnl.pdf*.

[9] See Society of Toxicology, Appointment and Participation of Scientists on Peer Review Panels and Scientific Advisory Boards, available at *http://www.toxicology.org/pm/AdvisoryBoard.asp*.

ments in a manner that addresses both public comments and the findings and recommendations of independent scientific peer review. At this time, upon receiving a SAB or NAS panel report, EPA unilaterally decides what elements to accept or reject—a practice that clearly has not worked, particularly given the NAS report on formaldehyde. Reviewing bodies should have an opportunity to address how the Agency intends to implement the recommendations.

III. Improving the Quality of Science by Leveraging Emerging Science and Technology

One of ACC's key objectives is to ensure that federal risk assessment policies and practices rely on 21st century knowledge of toxicology, biological modes of action, and advanced mechanistic technologies. There are dramatic changes underway in the science and technology of assessing chemical risks. These changes promise a revolution in the speed and accuracy with which chemical hazards, exposures, and risks are evaluated and managed.

While EPA has made important investments in developing new, highly reliable technologies that can speed chemical assessments, not all offices within EPA appear disposed to adopt these technologies when appropriate. Successful integration of emerging science and technology into risk assessment will require a concerted and methodic approach to evaluate the science and build consensus around their readiness.

The field of toxicology has grown more sophisticated as we have learned more about the biochemical mechanisms of toxicity and the differences between humans and test animals. New and exciting technologies for evaluating chemicals are emerging. In some cases, however, agencies are not well prepared to implement these new tools. Many federal agencies still cling to a set of conservative default assumptions little changed from the 1960s and '70s, and appear to be reluctant to adopt new technologies.

In ACC's view, it is critical that the Federal Government and the chemical industry be actively engaged in the transformation of chemical safety sciences. ACC member companies have made a significant, continuing investment in the ACC Long-range Research Initiative (LRI) to inform and advance this objective. ACC currently commits some $5 million annually [10] to the program, which is designed to help:

- Drive development of innovative approaches to assess and interpret health risks from low-dose exposures to chemicals and exposures to mixtures.
- Develop and apply new tools to interpret the explosion of biomonitoring and high-throughput testing data regarding human health risks.
- Accelerate the shift away from traditional high-dose animal toxicological testing by developing, validating, and promoting broad acceptance of approaches with greater relevance for humans.
- Translate emerging research outcomes for decisions about the safety of our chemicals by partnering with thought leaders from industry, government, academia, and public interest groups.

The LRI program's hallmark is the collaborative work to catalyze technological innovations in chemical safety sciences with the Federal Government, principally EPA and the National Institutes of Health. Examples of current collaborations between industry and governmental agencies include several ongoing projects between the Hamner Institute for Health Sciences and the EPA's National Center for Computational Toxicology (NCCT) and its National Center for Environmental Assessment (NCEA).

Other collaborative projects funded by the LRI extend ongoing work at the National Institute of Environmental Health Sciences (NIEHS). The unprecedented collaborations that the LRI has fostered among industry, governmental and regulatory agencies, and academia and demonstrates how an industry-sponsored initiative can effectively partner with other stakeholders to provide knowledge for science-informed decisions.

Among the collaborative research supported by the LRI program:

- Efforts to deliver state-of-the-art exposure science to advance the ExpoCast©component of EPA's ToxCast©program.
- Advance the interpretation of high-throughput data.

[10] ACC estimates that as a whole, the business of chemistry spent some $55 billion on research and development in 2010, the last year for which complete data are available. Slightly over 40% of that amount was spent on basic and applied research.

- Accelerate the paradigm shift in chemical risk assessment by incorporating ToxCast©data and toxicogenomics information into EPA's NexGen Risk Assessment program.
- Support validation of innovative biomarkers of cumulative exposures.
- Promote development of alternatives to animal testing.

The LRI program adheres to a stringent set of principles designed to ensure that the collaborative research we fund meets the highest standards for scientific excellence, transparency, and fairness.

The LRI program is focused not only on the new technologies for toxicological testing that are revolutionizing risk-based decision making, but is also helping to develop innovative biologically relevant approaches to understanding exposure. These technologies present an opportunity to develop a new paradigm for toxicity testing of chemicals, facilitate understanding of chemical hazards, and improve chemical safety evaluations. The current problem that they present is the growing gap between the advancements in these new technologies and the science to interpret and understand the emerging data.

In addition to providing state-of-the-art science and technology for chemical safety and risk assessments, LRI promotes development of tools that can be used by chemical companies for product innovation. For example, the LRI currently manages one of the most comprehensive portfolios of exposure projects that relates directly into efforts to (a) predictively develop exposure information, and (b) make existing exposure data widely available. Without these tools and data, there would be an increased likelihood that the next generation of risk assessments would be based entirely on hazard information or on overly conservative exposure assumptions.

ACC has suggested to EPA that the transition to new integrative and predictive molecular and computational techniques can be enhanced by focusing on critical issues such as:

- The need for an improved understanding of what short-timescale *in vitro* assays can foretell about the likelihood of long-timescale processes that lead to *in vivo* toxicity endpoints.[11] For example, specific response profiles in certain *in vitro* assays or combinations of assays could provide insights into potential toxicity endpoints, such as cancer, and may be useful in such decisions as prioritizing chemicals for additional testing. Considerable work is underway to enhance confidence in the use of these approaches and better interpret the results.
- The value of increased collaboration and engagement across the scientific community to interpret ToxCast©data for chemical prioritization. Increased transparency of relevant data and algorithms will allow EPA to leverage its intellectual resources and garner stronger understanding of and support for its approaches. EPA's NexGen Risk Assessment process already provides a similar mechanism to engage experts and stakeholders in the emerging science.

Conclusion

Ensuring that EPA decision making is firmly based on the use of high-quality science is critical to helping the Agency meet its obligation to protect human health and the environment. This can be achieved by common-sense reforms that will lead to more efficient and effective regulatory decisions. ACC looks forward to working with members of the Subcommittee to ensure that the science and processes that support the important regulatory work of the Federal Government meet the highest standards for quality and reliability.

Chairman HARRIS. Thank you very much.

I now recognize our fourth witness, Dr. Richard Belzer of Regulatory Checkbook.

STATEMENT OF DR. RICHARD BELZER, PRESIDENT, REGULATORY CHECKBOOK

Dr. BELZER. Chairman Harris, Ranking Member Miller, thank you for the invitation to testify. My views are my own and based on over 25 years of experience in this field.

[11] Judson, R., et al., *In Vitro* Screening of Environmental Chemicals for Targeted Testing Prioritization: The ToxCast Project, *Environmental Health Perspectives* 118:485–492 (2010).

Previous witnesses last November have testified that EPA's science is not well. The symptoms include the politicization of science, which occurs if agency policy officials change scientific information to benefit their preferred policy decisions; the scientization of policy, which occurs when agency risk assessors make policy decisions behind a veil of science; insufficient transparency reproducibility in agency risk assessments, perhaps best exemplified by the National Academy's recent report on formaldehyde; and dissatisfaction with EPA peer review, perhaps best revealed when Congress seeks peer review by the academy instead.

My analysis leads to a four-part diagnosis. First, the politicization of science is not something only EPA policy officials might do. EPA staff also politicize science, such as when they choose a desired result and seek only the science that supports it. Second, the scientization of policy is not something only EPA risk assessors might do. EPA officials scientize policy, such as when they say their policy decisions merely follow the recommendations of the scientists. Third, EPA risk assessments are not objective. This is not my opinion. An agency staff report says "EPA's policy is that risk assessment should not knowingly underestimate or grossly overestimate risks." Fourth, EPA peer review often does not serve the purposes for which it presumably was intended. EPA guidelines to the contrary, information quality is irrelevant to agency peer review. EPA always controls the charge and often the experts, who are often required to interpret science through EPA's policy lenses. Amazingly, peer reviewers often are charged with indirectly reviewing their own work. Fifth, EPA advisory committees are especially susceptible to politicizing science and scientizing policy. In April 2008, CASAC protested then-Administrator Johnson's decision to set the primary National Ambient Air Quality Standard for Ozone at .075 parts per million. CASAC members had every right to disagree with that decision on policy grounds, but they went off the rails, saying that it was their "consensus scientific opinion that his decision violated the Clean Air Act." Science cannot determine what is "requisite" to protect public health or what constitutes an "ample" margin of safety. Those lie beyond science.

I recommend several possible remedies for your consideration. First, Congress could require the EPA risk assessments, principal components, and key studies adhere to information quality principles and standards. Risk assessment should not be based on undisclosed data or models unless perhaps national security is at stake. It also should be objective. Deciding how much precaution should be accounted for in regulatory decisions is not part of an analyst's job. It belongs to the relevant agency official.

Second, Congress could revamp the EPA's peer review practices to explicitly require them to invest in information quality, to strictly limit peer reviews to science, and to remove the agency's ability to substantially control outcomes through procedural means.

Third, Congress could require advisory committees to "establish and maintain a clear conceptual distinction between assessment of risk and consideration of risk management alternatives" and ensure that their reports "clearly distinguish between the scientific basis and the policy basis for the conclusions and recommendations." That advice isn't mine. It was made by the National Acad-

emy committee that wrote the 1983 Red Book. It makes perfect sense for advisory committees. EPA officials making decisions should not have to struggle to discern where an advisory committee's scientific review ends and its policy advice begins.

These reforms would go a long way toward improving the quality of the EPA science. None of them would politicize science or scientize policy. Indeed, they would help prevent both by making them stick out like sore thumbs.

Thank you again for the opportunity to testify. I am happy to answer any questions when the time permits.

[The prepared statement of Mr. Belzer follows:]

PREPARED STATEMENT OF DR. RICHARD BELZER,
PRESIDENT, REGULATORY CHECKBOOK

Introduction

Chairman Harris, Ranking Member Miller, and Members of the Subcommittee, thank you for inviting me to testify on "Fostering Quality Science at EPA: Perspectives on Common-Sense Reforms." I am Dr. Richard B. Belzer, president of Regulatory Checkbook, a nonpartisan, nonprofit organization whose mission includes the promotion of quality improvements in science, economics, and information quality. [1]

I was elected Treasurer of the Society for Risk Analysis in 1998 and 2000, and earned its Outstanding Service Award in 2003. Previously I was named a Fellow of the Cecil and Ida Green Center for the Study of Science and Society. In 2009 and 2011, I was elected Secretary/Treasurer of a new professional organization, the Society for Benefit-Cost Analysis.

From 1988 through 1998, I was a career economist in OMB's Office of Information and Regulatory Affairs, where I reviewed many risk assessments that were integral parts of agencies' Regulatory Impact Analyses, for it is impossible to estimate costs and benefits without first estimating risks. My job was to examine agency analyses of the risks, costs, and benefits of draft regulations, and present to OMB officials and other Executive Office staff the most objective portrayal possible. Typically, this could not be done based on the risk assessments performed by the agencies. Agency risk assessments were purposefully biased to make risk appear greater than it was and the benefits of regulation appear greater than they were.

I have been president of Regulatory Checkbook since its founding in 2001. Regulatory Checkbook does not lobby or take public positions on substantive legislation or rule making; there is no shortage of organizations committed to doing that. Our sparsely populated niche is to seek improvements in the quality of risk assessment and economic analysis regardless of whether it tends to support or oppose specific regulatory actions. For that reason, we are interested in how quality is affected by various procedures, such as public comment, peer review, information quality principles and standards, and Executive oversight. No one has compensated Regulatory Checkbook or me for my testimony.

I am familiar with testimony previously provided to the Subcommittee. I will try to build on that and not be redundant.

Symptoms of the Quality Deficit

The purpose of these hearings has been to identify ways to improve the quality of science used by EPA in regulatory decision making. This, of course, implies that the state of the science for science at the Agency is not well. Numerous symptoms have been identified.

Politicization of Science or Scientization of Policy?

In March 2009, President Obama issued a Memorandum on Scientific Integrity stating, among other things, "Political officials should not suppress or alter scientific or technological findings and conclusions." [2] The President also made a commitment to transparency, saying, "If scientific and technological information is developed and

[1] The views expressed here are my own and do not necessarily represent those of Regulatory Checkbook.

[2] Barack Obama. "Scientific Integrity." Federal Register, 2009, 74(46), 10671–10672.

used by the Federal Government, it should ordinarily be made available to the public." It is my observation, based on over 20 years in risk assessment, that these principles are are universally agreed to—in principle. Putting them into policy turns out to be more difficult. It took 22 months for the White House Office of Science and Technology Policy—an office whose director the President directly supervises—to issue guidance implementing his memorandum.[3]

Moreover, OSTP's guidance is crafted with considerable structural and procedural ambiguity.[4] It calls for "policymakers [to] involve science and technology experts where appropriate," without clearly stating the circumstances where it wouldn't be. It directs agencies to select candidates for scientific positions "based primarily on their scientific and technological knowledge, credentials, experience, and integrity," thereby leaving wide open the option of giving substantial weight to their political affiliation or policy views.[5] It calls for "independent peer review by qualified experts," but only "where feasible and appropriate." The guidance says "political officials should not suppress or alter scientific or technological findings," but it does not actually generally prohibit this practice.[6] Only agency public affairs officers are expressly forbidden from doing this.[7]

The lesson from this is that it is much easier to announce a policy that seems straightforward than to implement it. It turns out that the intersection of policy and science is a lot more complicated than newspaper reporters, activists, and even candidates for president might think.

As the Subcommittee has heard, the 2009 report of the Bipartisan Policy Center's Science Policy Project discreetly pointed in a different direction—what is increasingly being called "the scientization of policy."[8] The BPC's Science Policy Project included former policy officials who, unsurprisingly, had a different perspective on the policy/science divide. Former OIRA Administrator Susan Dudley's testimony to the Subcommittee appears to be indicative of this, presumably reflecting her own experience.[9]

It turns out that this is an old issue. In 1986, Harvard Kennedy School professors Albert Nichols and Richard Zeckhauser published papers claiming that cancer risk was systematically overstated at EPA.[10] They wrote that this was done by Agency risk assessors for the purpose of influencing risk management decisions.[11]

In 1990, the Office of Management and Budget elaborated upon this problem in its *Regulatory Program of the United States Government*:

> Unfortunately, risk-assessment practices continue to rely on conservative models and assumptions that effectively intermingle important policy judgments within the scientific assessment of risk. Policymakers must make decisions based on risk assessments in which scientific findings cannot be readily differentiated from embedded policy judgments. This policy environment makes it difficult to discern serious hazards from trivial ones, and distorts the ordering

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[3] John P. Holdren. "Memorandum for the Heads of Executive Departments and Agencies: Scientific Integrity," Office of Science and Technoloy Policy, 2010.

[4] OSTP's guidance is mostly hortatory, saying agencies "should" do various things 19 times but never saying "shall" or "must." Eight times, these suggestions apply only if the agency judges them to be "appropriate." Four times, they apply only if "practicable."

[5] President Obama's memorandum did not include this qualification, stating: "The selection of scientists and technology professionals for positions in the executive branch should be based on their scientific and technological knowledge, credentials, experience, and integrity."

[6] The President's memorandum went further, saying "Political officials should not suppress or alter scientific or technological findings *and conclusions*" (emphasis added). The difference is surely not accidental, but its significance is not transparent. Possibly it shows that the White House has learned about the scientization of policy.

[7] Holdren (2010, p. 2). "In no circumstance may public affairs officers ask or direct Federal scientists to alter scientific findings."

[8] Bipartisan Policy Center. "Improving the Use of Science in Regulatory Policy," Washington, D.C.: Bipartisan Policy Center, 2009, p. 15. "[S]ome disputes over the 'politicization' of science actually arise over differences about policy choices that science can inform, but not determine."

[9] Susan E. Dudley. "Written Testimony Before the U.S. House of Representatives Committee on Science, Space, and Technology, Subcommittee on Energy and the Environment, Hearing on 'Fostering Quality Science at EPA: Perspectives on Common Sense Reforms,' " 2011.

[10] Albert L. Nichols and Richard J. Zeckhauser. "The Dangers of Caution: Conservatism in Assessment and the Mismanagement of Risk," Smith, Advances in Applied Micro-Economics: Risk, Uncertainty, and the Valuation of Benefits and Costs. Greenwich, Conn.: JAI Press, 1986a, 55–82. For a less technical version of this paper, see ————. "The Perils of Prudence: How Conservative Risk Assessments Distort Regulation." Regulation, 1986b, 10(6), 13–24.

[11] It is not clear, however, if this practice illustrates the scientization of policy, or the politicization of science by Agency staff rather than by Agency policy officials. It may have elements of both.

> of the Government's regulatory priorities. In some cases, the distortion of priorities may actually increase health and safety risks. [12]

OMB noted with approval the recommendation made by the committee that wrote the National Research Council's 1983 *Red Book*:

> Regulatory agencies should take steps to establish and maintain a clear conceptual distinction between assessment of risks and the consideration of risk management alternatives; that is, the scientific findings and policy judgments embodied in risk assessments should be explicitly distinguished from the political, economic, and technical considerations that influence the design and choice of regulatory strategies. [13]

Like the authors of the *Red Book*, OMB thought that fidelity to the *Red Book* recommendations was at least part of the solution. Though it was published more than 20 years ago, the problem OMB highlighted is the same thing that the BPC identified. [14]

While this is an old story, that does not mean it is outdated. In 2004, EPA published a staff report that explains its risk assessment policies and practices with signal clarity. This report acknowledges that EPA risk assessments are intentionally biased to overstate risk, and that this is done for the purpose of scientizing policy:

> [S]ince EPA is a health and environmental protective agency, EPA's policy is that risk assessments should not knowingly underestimate or grossly overestimate risks. [15]

All risk assessments err because they are estimates. What the EPA staff said is that they have a strong preference for erring on the side of overestimating risk, just not "grossly" overestimating it. They justify this preference based on the "health and environmental mission" of the Agency. This preference for overestimating the magnitude of risk is in addition to a preference for erring on the side of promulgating regulations that err on the side of overprotection.

It is worth reflecting on what this would mean if other federal agencies did the same thing:

- Would it be reasonable for engineers at the Federal Aviation Administration to intentionally overestimate the risk of air travel, perhaps by assuming all aircraft were as risky as the riskiest of them, and use those overestimates to motivate the FAA Administrator to promulgate more stringent safety regulations for all aircraft?
- Would it be reasonable for examiners in the Department of the Treasury to knowingly overstate the risk that a major bank might fail, in order to persuade the Secretary to take over that bank?
- Would it be reasonable for analysts at the Central Intelligence Agency to purposefully overstate the likelihood that the Islamic Republic of Iran will succeed in developing an fielding a nuclear weapon, thereby encouraging the President to launch a preemptive military attack?

To ask these questions is to answer them. It is the obligation of federal risk assessors, no matter where they work, to estimate risk as objectively as possible. They should never misuse the tools of risk assessment to manipulate decision makers into taking specific actions. Remarkably, the EPA staff report denies that the discretion

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[12] Office of Management and Budget. "Current Regulatory Issues in Risk Assessment and Risk Management," Regulatory Program of the United States, April 1, 1990–March 31, 1991. Washington, DC: Office of Management and Budget, 1990, 13–26. Full disclosure: I was the author of OMB's white paper. It is out of print but available on my Web site at*http://www.rbbelzer.com/uploads/7/1/7/4/7174353/omb_1990_risk_assessment.pdf*.

[13] National Research Council. Risk Assessment in the Federal Government: Managing the Process. Washington, D.C.: National Academies Press, 1983, p. 151.

[14] Bipartisan Policy Center (2009, p. 13). "Political decision makers should never dictate what scientific studies should conclude, and they should base policy on a thorough review of all relevant research and the provisions of the relevant statutes. But some disputes over the 'politicization' of science actually arise over differences about policy choices that science can inform, but not determine" (p. 13).

[15] U.S. Environmental Protection Agency Office of the Science Advisor. "An Examination of EPA Risk Assessment Principles and Practices; Staff Paper, EPA/100/B-04/001," 2004, p. 13. This does not necessarily mean that EPA always succeeds in overstating risk, or that there are not circumstances in which EPA does not understate risks, whether by accident or intent.

of Agency policy officials is constrained or misdirected by their practice of purposefully overestimating risk. [16]

Diagnosis

Whether science has been politicized or policy has been scientized is a useful distinction, but it is not complete. For example, it is assumed that science is politicized when policy officials invade the space of the scientists; and conversely, policy is scientized when agency scientists attempt to make policy decisions that Congress has delegated to agency heads.

This model is incomplete because Agency policy officials and risk assessors appear equally prone to do both. Sometimes, it is agency policy officials who scientize policy, such as when they try to attribute their policy choices to science. A policy official can avoid a lot of controversy if he is perceived as "merely following the science." [17]

Agency risk assessors may be willing or even pleased to go along, for it increases their power and authority inside the agency, in its battles with OMB, and for deflecting Congressional criticism. Thus, Agency risk assessors may have no more interest than Agency policy officials in revealing the extent to which officials have attributed policy decisions to science. Similarly, Agency officials and risk assessors alike may prefer not to make transparent the extent to which risk assessors actually make policy decisions under the cover of science.

Conflict arises, however, when Agency officials and risk assessors do not agree on policy. In these situations, Agency policy officials must first reclaim from Agency risk assessors the authority delegated to them by Congress to make policy decisions. It is easy for risk assessors to accuse their political bosses of politicizing science and nearly impossible for policy officials to defend themselves when the charge is false.

On the other hand, sometimes it is Agency risk assessors who politicize science. This happens when risk assessors choose the best available science that supports their preferred policy decision. Few policy officials would ever be the wiser, because it requires from them independent scientific expertise, substantial issue-specific knowledge, and more time than they have available.

The desired principles can be clearly expressed, if not easily implemented:

- Agency policy officials should be limited to making policy.
- Agency risk assessors should be limited to assessing risk.
- Risk assessment should be performed as objectively as possible and not be misused as a tool for achieving policy objectives through the back door.

Policy officials should stay out of science. They should allow science to inform their decisions but never allow it to control them, never hide behind it, and never tell scientists what conclusions to reach. They also should be persistent about asking risk assessors the right questions and getting second opinions from external authorities.

This goal begins with the *Red Book* recommendation and goes much further. Whereas the *Red Book* authors envisioned a smoothly interactive and iterative relationship between risk assessors and risk managers, with a "clear conceptual distinction" between science and policy "established and maintained," 30 years of history has shown that this model has either failed or cannot be implemented in a real-world regulatory agency. [18]

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[16] U.S. Environmental Protection Agency Office of the Science Advisor (2004, pp. 14–16).

[17] In previous testimony to this Subcommittee, EPA Administrator Jackson's decision to revise the 2008 National Ambient Air Quality Standard for ozone following the recommendations of the Clean Air Scientific Advisory Committee was described by a former CASAC chairman in similar but more strident terms. See Roger O. McClellan. "Written Testimony Before the U.S. House of Representatives, Committee on Science, Space, and Technology, Subcommittee on Energy and the Environment, Hearing on 'Quality Science for Quality Air,' " 2011.

[18] The author of this recommendation on behalf of the *Red Book* committee believes that EPA officials misinterpreted and misapplied it. See D. Warner North. "Reflections on the Red/Mis-Read Book, 20 Years After." *Journal of Human and Ecological Risk Assessment* , 2003, 9(5), 1145–1154. A somewhat different interpretation is that implementation as envisioned by the Committee was not administratively or politically feasible, an interpretation Professor Marchant appears to favor. See Gary E. Marchant. "Written Testimony Before the U.S. House of Representatives Committee on Science, Space, and Technology, Subcommittee on Energy and the Environment, Hearing on 'Fostering Quality Science at EPA: Perspectives on Common Sense Reform,' " 2011, p. 5. "As the role of science becomes ever more important to EPA's mission, and as the perception of EPA's science continues to be skeptical across the political spectrum, it may be time to consider a different model that institutionally separates the generation and assessment of science from the application of that science in regulatory decision making." Marchant

Continued

Information Quality Principles and Standards

In the following sections I focus on three areas in which EPA science has specific, notable deficiencies. These are information quality, peer review, and the confused role of federally chartered advisory groups.

In 2002, OMB issued governmentwide guidelines [19] to implement a statutory directive to improve information quality. [20] Like almost every other covered agency, EPA issued its own agency-specific guidelines before the October 1, 2002, deadline. [21] These guidelines commit EPA to adhere to certain standards of transparency, reproducibility, integrity, objectivity, and utility, and to establish administrative mechanisms whereby any person may seek and obtain the correction of noncompliant information. Indeed, EPA expressed the view that adhering to OMB's guidelines would not pose any challenge because its existing policies and procedures already ensured and maximized information quality. [22]

EPA's information quality guidelines say the Agency "is dedicated to the collection, generation, and dissemination of high quality information" and "seeks to foster the continuous improvement of existing information quality activities and programs." "In implementing these guidelines," EPA said "ensuring the quality of information is a key objective alongside other EPA objectives, such as ensuring the success of Agency missions, observing budget and resource priorities and restraints, and providing useful information to the public." [23] EPA also established well-defined administrative procedures for managing requests for correction and administrative appeals.

To be clear, information quality standards are expansive. They apply to "any communication or representation of knowledge such as facts or data, in any medium or form"—but not to policy decisions. Thus, they apply to risk assessment documents to the extent that they contain "representation[s] of knowledge such as facts or data." Because EPA officials claim that Agency risk assessment products are scientific, [24] there is no doubt that they are fully covered by applicable information quality guidelines.

The Subcommittee should be aware that EPA has exempted press releases and fact sheets from its information quality guidelines, which it describes as "[i]nformation of an ephemeral nature." Given that press releases and fact sheets are often the only information Congress and the press know about a complex risk issue, this exemption is obviously problematic. Further, the Subcommittee should be aware that EPA also exempts "[i]nformation presented to Congress as part of the legislative or oversight processes." [25] EPA testimony may have many desirable attributes, but adherence to information quality principles and standards is not one of them.

Many error correction requests submitted to EPA concern Agency risk assessments or components thereof, which the petitioner claims contain factual errors. Some requests are intended to seek full disclosure of data and methods to enable third parties to test for error, which both OMB's and EPA's information quality guidelines require. [26]

EPA committed to respond to requests for correction and appeals within 90 days. EPA's actual performance, however, has not lived up to these commitments. As of September 30, 2010, EPA's average response time for a request for correction was no less than 166 days. EPA's average response time for an appeal was no less than

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does not credibly explain how an external science production entity, such as his proposed Institute for Scientific Assessments, staffed and managed by full-time federal employees, would not succumb to the twin temptations of politicization and scientization.

[19] Office of Management and Budget. "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Notice; Republication." Federal Register, 2002, 67(36), 8452–8460.

[20] "Information Quality Act." 44 U.S.C. 3516 note. 2000.

[21] U.S. Environmental Protection Agency. "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency (EPA/260R-02-008)," 2002.

[22] U.S. Environmental Protection Agency (2002, pp. 10–14).

[23] U.S. Environmental Protection Agency (2002, p. 10).

[24] Paul Anastas. "Written Testimony Before the U.S. House of Representatives Committee on Science Space and Technology, Subcommittee on Oversight, Hearing on 'EPA's Integrated Risk Information System,' " 2011, p. 1. "IRIS assessments provide a *scientific* foundation for EPA decisions to protect public health across EPA's programs and regions under an array of environmental laws" (emphasis added).

[25] U.S. Environmental Protection Agency (2002, pp. 16–17).

[26] Some requests for correction are misguided attempts to change regulatory decisions. However, these requests are easy for EPA to dismiss on the ground that they concern matters that are exempt from the information quality paradigm.

316 days.[27] These figures are biased downward, and thus understate EPA's dilatory behavior, because they include requests and appeals that were still open at the end of FY 2010.[28]

In short, EPA's well-written administrative procedures have in practice failed to enable affected persons to "seek and obtain" the correction of information that does not comply with applicable information quality principles. Assuming it takes only 45 days to review EPA's response to a request for correction and file an appeal, it has taken on average more than 527 days for EPA's internal administrative process to run its course.

The substantive merits of these requests for correction vary, but it cannot be denied that many are highly meritorious. This can be seen by reviewing specific requests or logically inferred by the length of time EPA takes to respond. It should be easy for the Agency to quickly refute requests for correction that lack any merit, especially those which impermissibly seek to challenge Agency policy decisions. Conversely, requests for correction that are highly meritorious could be very hard to refute. If acknowledging error would undermine the legal standing or political legitimacy of a major regulation or an important EPA policy, no one should be surprised that the Agency takes a long time to decide how to respond, or that its responses are ambiguous, technically weak, misleading, or flatly wrong.

If an agency's response to a request for correction is incomplete, misguided, or lacks merit, the only recourse is an appeal within the agency. One cannot appeal to another Executive branch agency or seek review by a federal court. For that reason, public enthusiasm is limited even for submitting the most meritorious of error correction requests. Governmentwide, the number of requests for correction filed annually has declined by more than 75% since FY 2003. This is not because federal agencies have suddenly stopped disseminating erroneous information. It is because the agencies have responded to the Information Quality Act as if it were a potentially lethal virus and developed effective antibodies to prevent reinfection.

Peer Review

EPA is perhaps the federal agency that has committed the most to peer review. It conducts numerous peer reviews every year and has published a series of handbooks that guide Agency staff through the process.[29] Nevertheless, there appears to be widespread dissatisfaction with the actual performance of EPA peer review. This is self-evident given Congress' repeated decisions to supplement or even bypass EPA peer review in favor of the National Academy of Sciences.

Several problems afflicting EPA's peer review program are discussed below.

OMB's Bulletin on Peer Review Contains Obvious Errors

OMB issued governmentwide guidance on peer review in 2005.[30] This guidance is generally very useful and helpful. For example, it clearly states, "Peer reviewers shall be charged with reviewing scientific and technical matters, leaving policy determinations for the agency."

But OMB's guidance is especially weak exactly where it should have been strongest. Even though enhancing information quality was its raison d'etre, the guidance includes no requirement that agencies actually make information quality principles and standards an integral part of scientific peer review. OMB waffles, saying "[r]eviewers shall be informed of applicable access, objectivity, reproducibility and other quality standards under the Federal laws governing information access and quality."[31] In short, an EPA peer review complies with OMB's guidance as long as peer reviewers are *informed* about information quality, perhaps similar to one of the dozens of disclosure forms that must be provided at settlement when purchasing a

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[27] Richard B. Belzer. "Risk Assessment and Information Quality: An Empirical Study of Federal Agency Performance, 2010 Update," Society for Risk Analysis 2010 Annual Meeting, Salt Lake City, Ut., 2010. Since this paper was presented, EPA has received four new requests for correction.

[28] Eleven of 44 requests for correction and one of 16 appeals remained open at the end of FY 2010. The average response time, once these open actions were resolved, could only be greater.

[29] U.S. Environmental Protection Agency. "Peer Review Handbook (1st Ed.)," Washington, D.C.: U.S. Environmental Protection Agency Science Policy Council, 1988, ————. "Peer Review Handbook (2d Ed.)," Washington, D.C.: U.S. Environmental Protection Agency Science Policy Council, 2000, ————. "Peer Review Handbook (3rd Ed.)," Washington, D.C.: U.S. Environmental Protection Agency Science Policy Council, 2006.

[30] Office of Management and Budget. "Final Information Quality Bulletin for Peer Review." Federal Register, 2005, 70(10), 2664–2667.

[31] Office of Management and Budget (2005, p. 2675). Emphasis added.

house. There is no obligation for peer reviewers to do anything with this information.

OMB's guidance also includes a pair of extraordinarily large loopholes. First, OMB allows agencies to infer that studies published in peer-reviewed literature adhere to information quality principles and standards, including the crucial standards of presentational and substantive objectivity. This is bizarre. Adherence to these principles plays no role in journal review. If they knew about them, some editors of scholarly journals probably would consider information quality principles and standards wholly irrelevant or contradictory to the journal's mission. No matter; to OMB, peer review by a scholarly journal means the information contained in it is presentationally and substantively objective.

Second, OMB exempts reports of the National Academy of Sciences from any scrutiny whatsoever.[32] This is true even if there is no evidence that the review took account of applicable information quality principles and standards or there is incontrovertible evidence that the review violated these principles and standards.[33]

Information Quality Is AWOL from EPA Peer Review

EPA's latest Peer Review Handbook mentions information quality several places, but each reference is little more than boilerplate. Here is the most substantive reference I can find:

> The Agency recognizes peer review as a component of pre-dissemination review that complements and enhances the "objectivity" and "utility" of EPA's information products. The Agency recommends that offices conduct pre-dissemination reviews of information to ensure that the information is of appropriate quality before it is disseminated to the public. Pre-dissemination review is especially important for influential scientific information and highly influential scientific assessments.[34]

Notice that pre-dissemination review, which applicable information quality guidelines require agencies to perform, is reduced to a mere recommendation. The Handbook does not even include OMB's requirement that peer reviewers be "informed" about information quality principles and practices, so it should surprise no one when they aren't.

A reasonable inference is that EPA's Science Policy Council, the author of the Peer Review Handbook, does not want information quality to play a meaningful role in Agency peer review. Rather, the SPC hopes that by conducting peer review EPA will be treated *as if it had complied* with information quality principles and standards. This is wholly unjustified. Peer reviews conducted fully in compliance with the letter of the Handbook do not and cannot adhere to information quality principles and standards because those principles and standards are AWOL.

EPA's Science Advisory Board and the National Academy of Sciences are not solutions to this problem, for their reviews are no more likely to take information quality seriously. To take one obvious example, many observers have strongly endorsed Chapter 7 of the Academy's review of EPA's draft assessment of formaldehyde as a highly desirable step forward for improving the quality of IRIS assessments.[35] Perhaps it is, but the Academy's formaldehyde report does not include adherence to information quality principles and standards anywhere in its "road map." Indeed, the report never even mentions information quality, which suggests that the formaldehyde committee was utterly unaware of EPA's information quality guidelines.[36]

For this reason, the Chapter 7 "road map" might not be as helpful as its advocates hope. Most disturbingly, any Congressional directive to EPA insisting that it adhere

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[32] Office of Management and Budget (2005, p. 2675). "Principal findings, conclusions and recommendations in official reports of the National Academy of Sciences are generally presumed to have been adequately peer reviewed." OMB may have tried to hedge this blanket endorsement by limiting it to "principal findings," but the effectiveness of this hedge seems likely to be ephemeral.

[33] An incontrovertible violation would occur in any instance where the Academy gives policy advice. See the discussion surrounding footnote 30.

[34] U.S. Environmental Protection Agency (2006, p. 17).

[35] National Research Council. Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde. Washington, D.C.: National Academies Press, 2011.

[36] This does not mean the formaldehyde committee ignored information quality in its review. Several places in the report one can find discussions that indicate the committee wrestled with quality issues. Similarly, the "road map" has numerous references to "quality" because it wanted EPA to focus on "high-quality" studies. But the committee was bereft of a framework for defining quality because it apparently knew nothing about EPA's Information Quality Guidelines.

to the "road map" is an implicit invitation for the Agency to ignore information quality. Surely Congress did not intend this to happen.

Noncompliance with the Peer Review Handbook

There are numerous anecdotes suggesting that EPA peer reviews do not actually comply with the Peer Review Handbook. I am unaware of any systematic research on this question that would permit a more comprehensive inference. Clearly, such research could be valuable if it were conducted rigorously and independently of EPA.

Obviously, if research showed that EPA's adherence the Peer Review Handbook was as spotty as is the Agency's adherence to its information quality guidelines, this might go a long way toward explaining why there appears to be such widespread dissatisfaction with EPA peer review. Research also could discover if noncompliance with the handbook was random or causally associated with specific issues or regulatory programs.[37]

Excessive Agency Control

EPA's Peer Review Handbook makes clear that the Agency retains full control over the peer review charge and de facto control over the selection of peer reviewers. This is obviously true when a peer review is conducted by a panel established by EPA under the Federal Advisory Committee Act (FACA). But it is also true when the EPA conducts a workshop or contracts with a private company to conduct peer review. In these circumstances, EPA still controls the charge[38] and has the authority to veto the contractor's selection of peer reviewers.[39]

Nonscientific Content in EPA's Charge to Scientific Peer Reviewers

EPA peer review panels often are given a charge that includes crucial nonscientific content for which scientists have no special skills or insights. This occurs, for example, when a peer review panel is constrained to look at scientific information through the Agency's policy lenses. Common examples include the derivation of unit risk factors for carcinogens and Reference Doses for noncarcinogens, both of which have scientific content but are controlled by policy choices. When a scientific peer review panel is asked to review a proposed unit risk factor or Reference Dose, it is being asked to ratify the Agency's policy choices.

Insufficient Expertise

By virtue of their size, peer review panels may appear to be capable of reviewing all the relevant scientific questions posed by a draft risk assessment. This may not be true, however, if the issues presented are very broad and cross multiple disciplines. On a panel containing the 15 best external scientists, there may be just a couple who have crucial expertise related to a specific issue. If the number of scientific issues is large, reviewers will be assigned to those issues on which then have the most expertise. When it comes time to put the review together, panel members will be inclined to jealously guard the portion of the review they performed but defer completely to other members with respect to the rest. Instead of a single peer review performed by a panel of 15, the final report may be a half-dozen or more separate reviews, each performed by a small number of scientists, then repackaged as is it were a single document.

Excessive Expertise, of a Certain Form

It is becoming increasingly common to observe a peer review panel consisting of experts who are the authors of the research on which EPA has based its risk assessment. These experts are valuable and important, for they alone can ensure that the Agency has interpreted their work correctly. But they have no business serving on a peer review panel whose job will be to review whether these studies were performed correctly, whether they are the best available, whether they are objective, etc.

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[37] It is an open question whether this question is researchable. "Compliance" with a complex guidance document is not a binary state. The research task would involve a painstaking review of a representative sample of peer reviews. The sample would have to be large enough to have the statistical power to reject the null hypothesis.

[38] U.S. Environmental Protection Agency (2006, p. 59).

[39] U.S. Environmental Protection Agency (2006, p. 61).

This practice is disturbingly commonplace. The Clean Air Scientific Advisory Committee (CASAC), which performs a peer review function under Section 109(d)(2) of the Clean Air Act, is chaired by an author of studies on which EPA bases risk assessments for mortality caused by ambient air pollutants.[40] Four of the seven current members of CASAC have published research referenced in EPA's latest Integrated Science Assessment for ozone, which CASAC is responsible for reviewing. A scientist who formerly served on CASAC has testified before this Subcommittee that he was also a contributing author of multiple ISAs.[41] It is simply impossible for CASAC to independently peer review EPA risk assessment documents that rely on its members' own research. In fact, it violates EPA's Peer Review Handbook, for it represents the ultimate conflict of interest.[42]

Conflicts of Interest

Most observers seem to agree that conflicts of interest ought to be avoided if at all possible, and that peer review panels should manage bias by ensuring that a "balance of biases" is obtained. This principle is key to the National Academy's model, for example.[43]

I unapologetically take a different view.[44] We are saddled with conflict-of-interest policies that were written by lawyers in a way that makes them easy for lawyers to implement.[45] They treat appearances the same as facts, and minor financial interests related to for-profit employment more gravely than huge financial interests related to dependence on government research grants. Conflict-of-interest policies include measures to balance bias because scientific peer review panels routinely do more than review science—they opine on policy.

Public Participation Is Limited and Public Comments Are Ignored

EPA's Peer Review Handbook purports to welcome public participation in peer review, but it treats the public as a burden to be endured rather than a source of insight.[46] Similarly, the Handbook endorses the practice of making public comments available to peer reviewers,[47] but it does nothing to encourage, never mind require, that peer reviewers consider even the most significant scientific content of public comments. Unsurprisingly, public comments are routinely ignored in practice, and public participation is typically constrained to presentations lasting a few minutes.[48]

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[40] M.L. Bell, F. Dominici and J.M. Samet. "A meta-analysis of time-series studies of ozone and mortality with comparison to the national morbidity, mortality, and air pollution study." Epidemiology, 2005, 16(4), Michelle L. Bell, Aidan McDermott, Scott L. Zeger, Jonathan M. Samet and Francesca Dominici. "Ozone and Short-term Mortality in 95 US Urban Communities, 1987–2000." JAMA, 2004, 292(19), 2372–2378.

[41] George D. Thurston. "Written Testimony Before the U.S. House of Representatives, Committee on Science, Space, and Technology, Subcommittee on Energy and the Environment, Hearing on 'Quality Science for Quality Air': RE: The Science of Air Pollution Health Effects and The Role of CASAC in EPA Standard Setting," 2011, p. 2.

[42] U.S. Environmental Protection Agency (2006, p. 37). "Since it would probably result in a perceived, if not real, conflict of interest, the group that is generating the work product usually cannot conduct or perform the peer review of its own work product."

[43] The National Academies. "Policy on Committee Composition and Balance and Conflict of Interest," The National Academies, 2003.

[44] A more extensive discussion of the contrasts between scholarly and governmental peer review can be found in a paper I wrote for a 2002 conference sponsored by the Society for Risk Analysis. See Richard B. Belzer. "Interests and Incentives in Government Peer Review," Conflict, Consensus, and Credibility: A Forum on Regulatory Peer Review, Alexandria, VA, 2002. Available at *http://www.rbbelzer.com/presentations.html#2002*.

[45] Andrew Stark. Conflict of Interest in American Life. Cambridge, Mass.: Harvard University Press, 2000.

[46] U.S. Environmental Protection Agency (2006, p. 49). "To ensure that public participation does not unduly delay activities, Offices should specify time limits for public participation throughout the peer review process."

[47] U.S. Environmental Protection Agency (2006, p. 74 [distribution to peer reviewers is required for "influential scientific assessments"]). See also p. 49: "When employing a public comment process as part of the peer review, Offices should, whenever practical, provide peer reviewers with access to public comments that address significant scientific or technical issues."

[48] Robert F. Phalen. "Written Testimony Before the U.S. House of Representatives, Committee on Science, Space, and Technology, Subcommittee on Energy and the Environment, Hearing on 'Quality Science for Quality Air': The CASAC–PM Committee—Setting Air Quality Standards," 2011. "The public comments were not weighed and discussed by CASAC–PM in spite of the fact that most were well-reasoned and relevant. If the agenda included time for discussion of public comments and formal acceptance or rejection of their recommendations, the process might be improved."

This means peer reviews of draft EPA risk assessments tend to be dialogues between the peer review panel and Agency staff, who might (or might not) have written (part of) the document. Unless they happen to be members of the peer review panel, primary researchers are rarely present and would in any case be relegated to cameo presentations during the limited time permitted for public comment. [49]

In the section below on remedies, I describe an alternative to this zoological style peer review in which public participation is taken seriously, and primary researchers have the lead in presenting scientific information but do not play a role in evaluating it. [50]

Federally Chartered Advisory Committees

Even more than peer review panels, advisory committees are susceptible to politicizing science and scientizing policy. To the extent that they can locate a scientific rationale for the advice they want to provide, it can only make their recommendations more persuasive. Like Congress, the public often fondly hopes for scientific answers to difficult policy questions. If a policy choice can be made to appear scientific, it may have a much easier time gaining public acceptance.

One of the most striking examples of scientization occurred in 2008, after EPA finalized its revision to the ozone National Ambient Air Quality Standard. CASAC sent Administrator Stephen Johnson an unsolicited letter strenuously disagreeing with his decision. By itself, this might have been noteworthy but it should not have been overly controversial. After all, advisory committees that are independent of an agency's control must be free to offer whatever policy advice they see fit, and Agency officials are never obligated to accept policy recommendations from advisory committees.

But CASAC went much, much further. CASAC misrepresented its policy advice as science:

> It is the Committee's consensus *scientific* opinion that your decision to set the primary ozone standard above this range [0.060 to 0.070 ppm] fails to satisfy the explicit stipulations of the Clean Air Act that you ensure an adequate margin ofsafety for all individuals, including sensitive populations. [51]

This is wrong in multiple ways, and it should have drawn widespread opprobrium instead of acclaim. Science might be able to determine what human health effects occur at defined ozone concentrations, though even this ability becomes suspect as concentrations approach background. But it is impossible for science to determine what concentration is "requisite to protect the public health" or determine what constitutes "an adequate margin of safety." "Requisite" and "adequate" are squishy policy terms; they cannot be defined scientifically. But CASAC attempted to scientize air pollution policy—to make it appear as if science is the rightful venue for determining the meaning of "requisite" and "adequate." Equally disturbing, CASAC attempted to arrogate the authority to make these policy decisions despite knowing full well that Congress delegated them to the Administrator.

This incident exposed a serious defect in the Clean Air Act's procedures, one that has lessons for advisory committees generally. By asking CASAC to review the scientific record to ensure that it "accurately reflects the latest scientific knowledge," [52] but simultaneously ask CASAC to give policy advice to the Administrator concerning what the standard ought to be, Congress practically invited CASAC to scientize policy. For CASAC members, it was their scientific credentials and expertise that gave them power, which they willfully abused. And because they did so, it is entirely reasonable to be skeptical about the quality of CASAC's scientific review. Did CASAC also politicize the science to make it support members' personal opinions about air pollution policy? Has anyone conducted a rigorous review to find out?

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[49] See, e.g., William C. Adams. "Public Comment to CASAC Ozone Review Panel Teleconference." Available at *http://www.epa.gov/sab/pdf/pub_comments_03-05-07_dr_wm_adams_uc-davis.pdf*; accessed January 29, 2012.

[50] I use the term zoological to describe EPA peer reviews to reflect the fact that the public's role is strictly observational. Even tapping on the glass is prohibited.

[51] Rogene Henderson. "April 7, 2008, Letter to Stephen L. Johnson from CASAC on 'Clean Air Scientific Advisory Committee Recommendations Concerning the Final Rule for the National Ambient Air Quality Standards for Ozone,' " CASAC April 7, 2008, Letter on O_2 NAAQS. Washington, D.C.: U.S. Environmental Protection Agency Office of the Science Advisory Board, 2008, p. 2. Emphasis added.

[52] See, e.g., "Clean Air Act." 44 U.S.C. 7401 et seq. 1970. See § 7409(d)(2)(B), referring back to §108(a)(2).

Some Possible Remedies

Several remedies can be envisioned that follow from my diagnosis.

Information Quality

The key problem noted above is that EPA does not adhere to its information quality guidelines. It largely ignores its procedural and substantive commitments. It does not respond in a timely manner to requests for correction and appeals. When it does respond, it tends to obfuscate. When it acknowledges errors, it does not correct them.

These deficiencies are no doubt caught up in program offices' desire to defend their past or pending regulatory decisions. But that cannot explain the Agency's unwillingness to adhere to information quality principles and standards in its science program, which EPA leadership claims is not regulatory. [53]

A reasonable inference is that EPA's research programs may be infected by both scientization (the desire to make policy decisions through science) and politicization (the abuse of science for policy purposes). Requiring EPA research programs to fully adhere to information quality principles and standards would go a long way toward overcoming these problems if they exist. If they do not exist, then full adherence to information quality principles and standards would earn EPA the credibility it believes it is deserved, and once and for all refute its many critics.

There are simple reforms that Congress could make that would breathe life into the information quality paradigm, thereby achieving a dramatic improvement in the quality of EPA science. In particular, Congress could require one or more of the following:

Require Full Disclosure of All Data, Models and Methods for Any Study Used as the Basis for a Risk Assessment or Component Thereof

There appears to be a broad consensus in favor of transparency and reproducibility, the two procedural information quality standards. Under applicable information quality guidelines, data, models, and methods must be fully disclosed such that qualified third parties can reproduce the agency's results and obtain essentially the same result. If third parties are unable to even make such an attempt, then the agency work product is per se insufficiently transparent and violates applicable standards. If third parties can make the attempt but cannot reproduce EPA's results, then the information should be presumed to fail the objectivity test. In either case, the information involved should not be disseminated, much less used for risk assessment. [54]

Agencies avoid the full force of this transparency standard by claiming, correctly, that published articles in scholarly journals do not disclose enough information to meet the transparency and reproducibility standards. Congress can best solve this problem by altering incentives.

Contracting regulations already permit federal agencies to demand that recipients of federal research funds submit their data upon request. Unfortunately, agencies still have the discretion not to ask, and they often do so precisely to avoid having to disclose the information to the public as the Shelby Amendment otherwise requires. [55] Congress could relieve federal agencies of this conundrum by requiring

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[53] This principle is highlighted in previous testimony to the Subcommittee without reference to applicable information quality guidelines. See Anastas (2011, p. 1). "IRIS assessments provide a scientific foundation for EPA decisions to protect public health across EPA's programs and regions under an array of environmental laws. While not regulations, IRIS assessments are critical to many Agency decisions. After becoming Administrator in early 2009, Administrator Jackson reviewed the IRIS program and asked the Office of Research and Development (ORD) in May 2009 to implement a new IRIS process that would revitalize the program and make it more responsive to the needs of the Agency. The aim of the new process was to ensure the highest level of scientific quality, integrity, transparency, and timeliness."

[54] The scientific information classification scheme recommended to the Subcommittee by Dr. Moghissi also has significant merit as a way to identify where scientific knowledge is weakest so that investments in research could be targeted to have the greatest value. See A. Alan Moghissi. "Written Testimony Before the U.S. House of Representatives, Committee on Science, Space, and Technology, Subcommittee on Energy and Environment, Hearing on 'Fostering Quality Science at EPA: Perspectives on Common-Sense Reform:' The Need for Regulatory Science Transparency at the EPA," 2011.

[55] Pub. L. 105–277, 112 Stat. 2681–495: "That the Director of OMB amends Section ——.36 of OMB Circular A-110 to require Federal awarding agencies to ensure that all data produced under an award will be made available to the public through the procedures established under the Freedom of Information Act." OMB's implementation of this provision was highly controver-

them to obtain research data if they want to use a federally funded study as the basis for risk assessment. Requiring disclosure imposes only trivial costs on the agencies and does not violate the contractual terms of any federally funded researcher. No burden would be imposed on anyone if the agency did not want to use a federallyfunded study as the basis for risk assessment, and no researcher would be compelled to accept federal research funds to conduct a study likely to be useful in risk assessment.

If an agency wants to rely on a study that was funded by another party, whether that be a State, business, trade association, or nongovernmental organization, nothing currently prevents the agency from asking that this information be supplied, nor is there any general legal barrier to the other party providing it. States, businesses, trade associations, and nongovernmental organizations that want their research to be used for public policy should happily volunteer to provide it. Some do.

Moreover, an ever-increasing number of scholarly journals now require disclosure as a condition for publication. Congress can expedite this trend by prohibiting federal agencies from basing risk assessments on studies published by journals that do not practice full disclosure. Researchers who want their work to influence policy will seek publication in journals that require disclosure.

Require That Any Study Used as the Basis for a Risk Assessment or Component Thereof Adhere to Substantive Information Quality Standards

Information quality standards, particularly the standards of presentational and substantive objectivity, should not apply to all scientific research. Exploratory, hypothesis-generating research often has merit, but by its nature it often cannot comply. However, hypothesis-testing research should always comply, particularly if it is going to be used for risk assessment. By requiring crucial studies to adhere to substantive information quality standards, much of the controversy over study selection could be eliminated.

Notice that I would not require prior publication in a peer-reviewed journal or give special weight to such studies. Journals publish studies for many reasons, some of which are incompatible with their use in risk assessment. Full disclosure is a much better threshold requirement. Deference should be given to studies that, after full disclosure, have been reproduced and not refuted.

Require That Agency Risk Assessments or Components Thereof Adhere to Substantive Information Quality Standards

While it is crucial that key studies adhere to information quality standards, it is not sufficient. Considerable analysis is performed subsequent to the selection of key studies, so it is essential that information quality standards also apply to risk assessments and other derivative work products.

In practice, this would mean that cancer risk assessments (including those containing unit risk values) and noncancer risk assessments (including those containing Reference Doses or Reference Concentrations) would have to adhere to the information quality paradigm.

In the short run, this would be very difficult for EPA because, as I noted above, it is the published policy and practice of the Agency not to produce objective risk assessments. In the long run, however, this requirement would unleash a torrent of new research into more objective risk assessment methods. Currently, there is very little "market demand" for objective methods because EPA is essentially a monopsonist in this "market.' That is, EPA is the only buyer; as long as EPA does not want objective risk assessment methods, the market will not supply any.

Enforcement

If Congress were to require EPA research programs to adhere to information quality principles and standards, it would have to devise a way to enforce this requirement. We know that hortatory appeals and executive certifications do not work. We also know that inviting judges to "do science" cannot be much of an improvement, for they are just as susceptible to the temptation to politicize science. Even if judicial review never erred, it also would be an expensive remedy that only a few could utilize.

One way to reduce the cost of judicial review is to narrowly tailor it to take advantage of the courts' comparative advantage in administrative procedure. Thus,

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sial among recipients of federal research funds who considered the data they collected to be their private intellectual property.

courts might be authorized to render opinions on agency adherence to published information quality principles and practices, but they must be kept away from substantive scientific disputes.

Peer Review

Several specific reforms of EPA peer review could be considered.

Explicitly Require Peer Reviews to Address Information Quality

The reforms recommended above in the section on information quality would go a long way to solving this problem. They would make clear that adherence to information quality principles and standards is not optional for studies on which EPA intended to base a risk assessment, or for risk assessments themselves.

As I noted above, EPA's Peer Review Handbook gives short shrift to information quality. Congress could remedy this by explicitly requiring peer reviews to include rigorous information quality review. This should be done early in the process so that EPA does not commit itself to basing risk assessments on noncompliant studies. EPA could be sure early on that the studies on which it intends to rely are fully compliant and will not be the subject of a spurious later controversy. Information quality review also should be done later to ensure that subsequent analyses performed by the Agency also comply. Waiting until EPA has already published a draft risk assessment may be too late, for by that time Agency risk assessors often have dug in their heels.

Considerable effort would be needed to train scientist-peer reviewers in information quality principles and standards, or alternatively, establish information quality as a distinct discipline that must be represented on every peer review panel. I prefer training scientist-peer reviewers so that they become better equipped to detect information quality errors as a regular part of their own professional discipline. This has external benefits insofar as it would introduce concern for information quality into journal peer review, and thus into scholarly research destined for journal publication.

Strictly Limit Scientific Peer Reviews to Science

It might seem superfluous to make such a requirement explicit, but the record shows that it is needed. Peer reviewers have incentives to scientize policy, and EPA staff have incentives to ask peer reviewers to conduct their reviews in ways that at least implicitly ratify embedded policy decisions. By strictly limiting scientific peer reviews to science, it would be much easier to discern when any actor in the peer-review process—EPA staff, peer reviewers, and public commenters alike—has exceeded the charge.

At a practical level, this would mean removing so-called "science policy" issues from peer review. This is highly desirable, for it is within the domain of "science policy" that politicization and scientization are most likely to occur. Also, removing "science policy" would make peer review a much easier task for scientists to perform. It would improve the scientific quality of the peer review charge, for controversies over embedded policy choices within the charge would go away.

If policy issues were removed from the scope of scientific peer review, the importance of balancing bias among members of a peer review panel would appreciably diminish. Instead of worrying about balancing different policy views, greater attention could be devoted to ensuring that peer review panels have diverse intellectual perspectives. When there is a coincidence of intellectual interests among peer reviewers or between the panel and the Agency, as the current regime encourages, the result can be an echo chamber.[56]

Make the Selection of Reviewers and the Charge Independent of the Agency

It's a well-known secret that the ability to select peer reviewers and write the charge creates the opportunity to control the outcome. For this reason, EPA should not control the charge and peer reviewers should not be selected by EPA or its contractors.[57] In its Peer Review Handbook, EPA displays a high degree of skepticism

[56] The echo is deafeningly loud when peer reviewers also share the same policy or "science policy" views as Agency staff—yet another good reason for strictly limiting scientific peer review to science.

[57] It should be expected that contractors who want to maintain their business relationships with EPA are cognizant of EPA's desires with respect to panel selection.

about external parties conducting peer reviews of their own work products.[58] It is therefore hardly unreasonable for others to be similarly skeptical of peer reviews of EPA work products conducted by EPA.[59] A simple expedient might be to establish and maintain lists of qualified, independent panel members for each discipline and select the requisite number of members from each list by lottery.

In 2006, Regulatory Checkbook organized and conducted a scientific review that I believe follows another superior model that EPA could adopt. We followed OMB's draft peer review guidelines,[60] which were much stronger than the final version. We strictly limited the review to science—where possible, only primary scientific research was considered—and excluded all manner of policy considerations, such as the derivation of a unit risk factor. We focused on just four major scientific questions, thus conserving resources to address only the most important issues, with a separate peer review panel for each. Rather than control information exchange, we delegated that responsibility to universally respected, bona fide subject matter experts. So long as it did not stray into policy, we encouraged open discussion among all participants, including members of the public.[61] Finally, to avoid any interference by the sponsors, we established a Planning Committee whose role was to select the issues to be examined, select the subject matter experts and peer review panelists, write the charge, and coordinate the submission of the final reports for consideration by a scholarly journal subject to another round of peer review.[62]

Federally Chartered Advisory Committees

A key lesson for Congress from the CASAC experience is to refrain from asking advisory committees to perform tasks that are inherently in conflict, such as conducting scientific review and giving policy advice.

Where this cannot be avoided, such as existing committees whose charters it is impracticable to change, advisory committees should be required to abide by relevant *Red Book* recommendations. They should "establish and maintain a clear conceptual distinction between assessment of risks and consideration of risk management alternatives," and ensure that their reports "clearly distinguish between the scientific basis and the policy basis" for their conclusions and recommendations. This can be easily enforced, such as by authorizing the EPA Administrator to ignore reports from advisory committees that demonstrably do not comply. The threat of being ignored is a powerful incentive.

What Agency Officials Can Do Without Congressional Action

I do not want to convey the impression that nothing can be done unless Congress acts. This is clearly not true. Obviously, EPA officials could, if they wanted to, insist that staff adhere to applicable information quality principles and standards. EPA officials could, if they wanted to, direct the Science Policy Council to amend the Peer Review Handbook to explicitly include information quality review. They could, if

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[58] See U.S. Environmental Protection Agency (2006, p. 72).

[59] EPA appears to object even to peer reviews paid for by third parties where there is ample evidence of independence or no evidence of third-party control.

[60] Office of Management and Budget. "Proposed Bulletin on Peer Review and Information Quality." Federal Register, 2003, 68, 54023–54029.

[61] We did not follow EPA's practice of limiting the participation of independent experts to staged five-minute didactic presentations.

[62] Richard B. Belzer, James S. Bus, Ercole L. Cavalier, Steven C. Lewis, D. Warner North and Richard C. Pleus. "The naphthalene state of the science symposium: Objectives, organization, structure, and charge." *Regulatory Toxicology and Pharmacology*, 2008, 51(2(1)), 1–5; Kenneth T. Bogen, Janet M. Benson, Garold S. Yost, John B. Morris, Alan R. Dahl, Harvey J. Clewell III, Kannan Krishnan and Curtis J. Omiecinski. "Naphthalene metabolism in relation to target tissue anatomy, physiology, cytotoxicity and tumorigenic mechanism of action." *Regulatory Toxicology and Pharmacology*, 2008, 51(2(1)), 27–36; David Brusick. "Critical assessment of the genetic toxicity of naphthalene." *Regulatory Toxicology and Pharmacology*, 2008, 51(2(1)), 37–42; David Brusick, Mitchell S. Small, Ercole L. Cavalieri, Dhrubajyoti Chakravarti, Xinxin Ding, David G. Longfellow, Jun Nakamura, Eleanor C. Rogan and James A. Swenberg. "Possible genotoxic modes of action for naphthalene." *Regulatory Toxicology and Pharmacology*, 2008, 51(2(1)), 43–50; Fumie Y. Griego, Kenneth T. Bogen, Paul S. Price and Douglas L. Weed. "Exposure, epidemiology and human cancer incidence of naphthalene." *Regulatory Toxicology and Pharmacology*, 2008, 51(2(1)), 22–26; D. Warner North, Kamal M. Abdo, Janet M. Benson, Alan R. Dahl, John B. Morris, Roger Renni and Hanspeter Witschi. "A review of whole animal bioassays of the carcinogenic potential of naphthalene." *Regulatory Toxicology and Pharmacology*, 2008, 51(2(1)), 6–14; Paul S. Price and Michael A. Jayjock. "Available data on naphthalene exposures: Strengths and limitations." *Regulatory Toxicology and Pharmacology*, 2008, 51(2(1)), 15–21.

they wanted to, insist that Agency peer reviews comply with the Peer Review Handbook.

EPA officials also could, if they wanted to, require Agency peer reviews to be strictly limited to science. It would take hardly any effort at all for EPA officials to modify the charters of Agency advisory committees and specifically include within each a requirement to abide by the *Red Book*.

In short, most of the reforms I have proposed actually require Congress to do anything. The reason why the Subcommittee is conducting oversight and considering legislation, however, is that EPA officials—officials appointed by Democratic and Republican presidents alike—have not made any of these reforms.

Final Remarks

My diagnosis of the problems afflicting EPA science is not novel; indeed, I have specifically cited papers published in 1986 that make many of the same points.

To the best of my knowledge, Congress has never politicized EPA science by, for example, requiring it to estimate risk inaccurately or in a misleading way.[63] These are things EPA has done on its own, often by misusing the tools of risk assessment (the estimation of what risk is) to justify particular risk management decisions (the policy determination of what risk *ought to be*).[64]

In this way, EPA risk assessors and other staff have scientized policy and politicized science. They have scientized policy by claiming that science can answer questions that science can inform but not decide. They have politicized science by choosing not to estimate risk accurately. By scientizing policy, Agency risk assessors and other staff have taken away from Agency officials the authority and responsibility, delegated by Congress, to make policy decisions. They take away from policy officials alternatives that are well within the range of plausible interpretations of their statutory directives.[65]

The remedies I have proposed should not be controversial if the goal is to improve scientific quality while preserving the Agency's legitimate discretion under the various laws Congress has directed it to implement. They are grounded in the ideals of the National Academy's 1983 *Red Book*, yet recognize that the *Red Book* model has either failed or cannot be implemented. Instead of "establishing and maintaining a clear conceptual distinction between assessment of risks and the consideration of risk management alternatives," I believe it is time to effect a full and complete separation. I believe this is essential to restore science to its rightful place, freeing it from politicization, while at the same time aggressively policing the boundary between science and policy to ensure that policy making also is free from scientization.

Some recommend removing risk assessment from EPA, believing that it is simply not possible for science to be performed within "the political cauldron" of EPA because its "messy mix of politics, policy, economics, law, interests, and values" make it "not a good environment in which to develop and evaluate science."[66] I understand the sentiment but I am not ready to give up, nor is it clear to me that giving up is a realistic option.

Thank you again for the opportunity to testify today on this important subject. I would be pleased to answer any question that members of the Subcommittee might have.

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[63] In its 2004 report explaining and defending its risk assessment policies and practices, EPA staff say that Congress has, in fact, directed EPA to use risk assessment methods that are "protective" (i.e., tend to overstate risk). See National Research Council (1983, pp. 151, 153). However, the report does not provide a single example of a statutory provision requiring EPA to estimate risk in a biased manner. Every example given is either irrelevant to the question or it conflates risk assessment with risk management. See ibid., pp. 14–16.

[64] U.S. Environmental Protection Agency Office of the Science Advisor (2004,p. 14). "Congress establishes legal requirements that generally describe the level of protectiveness that EPA regulations must achieve and, infrequently, Congress imposes specific risk assessment requirements." "EPA seeks to adequately protect public and environmental health by ensuring that risk is not likely to be underestimated" (emphasis in original).

[65] EPA staff deny this, but unconvincingly. "[A]ny science policy position or choice used in the risk assessment process does not direct the risk assessment itself toward a specific risk management decision, e.g., the use of a specific risk estimate," they write. "Rather, the risk assessment informs the decision maker about the potential risks and uncertainties around the risk estimate(s). These characterized risks are then considered in light of the other factors before a decision is made." (ibid., p. 13). Except that it misinforms decision makers, making it harder for them to take account of "other factors."

[66] U.S. Environmental Protection Agency Office of the Science Advisor (2004,p. 11). Professor Marchant advocates removing the production and review of science from EPA's jurisdiction: "it would be best if the science was developed and evaluated separately, and in particular in a separate institutional context, from the more political decision-making process."

References

1. "Clean Air Act." 44 U.S.C. 7401 *et seq*. 1970.

2. "Information Quality Act." 44 U.S.C. 3516 note. 2000.

3. Adams, William C. "Public Comment to CASAC Ozone Review PanelTeleconference." Available at*http://www.epa.gov/sab/pdf/pub_comments_03-05-07_dr_wm_adams_uc-davis.pdf*; accessed January 29, 2012.

4. American Association for the Advancement of Science. "AAAS Policy Brief: Access to Data." Available at*http://www.aaas.org/spp/cstc/briefs/accesstodata/index.shtml*;accessed January 27, 2012.

5. Anastas, Paul. "Written Testimony Before the U.S. House of Representatives Committee on Science Space and Technology, Subcommittee on Oversight, Hearing on 'EPA's Integrated Risk Information System,' " 2011.

6. Bell, M.L.; F. Dominici and J.M. Samet. "A meta-analysis of time-series studies of ozone and mortality with comparison to the national morbidity, mortality, and air pollution study." *Epidemiology*, 2005, 16(4).

7. Bell, Michelle L.; Aidan McDermott; Scott L. Zeger; Jonathan M. Samet and Francesca Dominici. "Ozone and Short-term Mortality in 95 US Urban Communities, 1987–2000." *JAMA*, 2004, 292(19), 2372–2378.

8. Belzer, Richard B. "Interests and Incentives in Government Peer Review." Conflict, Consensus, and Credibility: A Forum on Regulatory Peer Review, Alexandria, Va., 2002.

9. ————. "Risk Assessment and Information Quality: An Empirical Study of Federal Agency Performance, 2010 Update." Society for Risk Analysis 2010 Annual Meeting, Salt Lake City, Ut., 2010.

10. Belzer, Richard B.; James S. Bus; Ercole L. Cavalier; Steven C. Lewis; D. Warner North and Richard C. Pleus. "The naphthalene state of the science symposium: Objectives, organization, structure, and charge." *Regulatory Toxicology and Pharmacology*, 2008, 51(2(1)), 1–5.

11. Bipartisan Policy Center. "Improving the Use of Science in Regulatory Policy," Washington, D.C.: Bipartisan Policy Center, 2009.

12. Bogen, Kenneth T.; Janet M. Benson; Garold S. Yost; John B. Morris; Alan R. Dahl; Harvey J. Clewell III; Kannan Krishnan and Curtis J. Omiecinski. "Naphthalene metabolism in relation to target tissue anatomy, physiology, cytotoxicity and tumorigenic mechanism of action." *Regulatory Toxicology and Pharmacology*, 2008, 51(2(1)), 27–36.

13. Brusick, David. "Critical assessment of the genetic toxicity of naphthalene." *Regulatory Toxicology and Pharmacology*, 2008, 51(2(1)), 37–42.

14. Brusick, David; Mitchell S. Small; Ercole L. Cavalieri; Dhrubajyoti Chakravarti; Xinxin Ding; David G. Longfellow; Jun Nakamura; Eleanor C. Rogan and James A. Swenberg. "Possible genotoxic modes of action for naphthalene." *Regulatory Toxicology and Pharmacology*, 2008, 51(2(1)), 43–50.

15. Dudley, Susan E. "Written Testimony Before the U.S. House of Representatives Committee on Science, Space, and Technology, Subcommittee on Energy and the Environment, Hearing on 'Fostering Quality Science at EPA: Perspectives on Common Sense Reforms,' " 2011.

16. Griego, Fumie Y.; Kenneth T. Bogen; Paul S. Price and DouglasL. Weed. "Exposure, epidemiology and human cancer incidence of naphthalene." *Regulatory Toxicology and Pharmacology*, 2008, 51(2(1)), 22–26.

17. Henderson, Rogene. "April 7, 2008, Letter to Stephen L. Johnson from CASAC on 'Clean Air Scientific Advisory Committee Recommendations Concerning the Final Rule for the National Ambient Air Quality Standards for Ozone,' " CASAC, April 7, 2008, Letter on O_2 NAAQS. Washington, D.C.: U.S. Environmental Protection Agency Office of the Science Advisory Board, 2008.

18. Holdren, John P. "Memorandum for the Heads of Executive Departments and Agencies: Scientific Integrity," Office of Science and Technoloy Policy, 2010.

19. Marchant, Gary E. "Written Testimony Before the U.S. House of Representatives Committee on Science, Space, and Technology, Subcommittee on Energy and the Environment, Hearing on 'Fostering Quality Science at EPA: Perspectives on Common Sense Reform,' " 2011.

20. McClellan, Roger O. "Written Testimony Before the U.S. House of Representatives, Committee on Science, Space, and Technology, Subcommittee on Energy and the Environment, Hearing on 'Quality Science for Quality Air,' " 2011.

21. Moghissi, A. Alan. "Written Testimony Before the U.S. House of Representatives, Committee on Science, Space, and Technology, Subcommittee on Energy and Environment, Hearing on 'Fostering Quality Science at EPA: Perspectives on Common Sense Reform:' *The Need for Regulatory Science Transparency at the EPA*," 2011.

22. National Research Council. *Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde*. Washington, D.C.: National Academies Press, 2011.

23. ————. *Risk Assessment in the Federal Government: Managing the Process*. Washington, D.C.: National Academies Press, 1983.

24. Nichols, Albert L. and Richard J. Zeckhauser. "The Dangers of Caution: Conservatism in Assessment and the Mismanagement of Risk," V. Kerry Smith, *Advances in Applied Micro-Economics: Risk, Uncertainty, and the Valuation of Benefits and Costs*. Greenwich, Conn.: JAI Press, 1986a, 55–82.

25. ————. "The Perils of Prudence: How Conservative Risk Assessments Distort Regulation." *Regulation*, 1986b, 10(6), 13–24.

26. North, D. Warner. "Reflections on the Red/Mis-Read Book, 20 Years After." *Journal of Human and Ecological Risk Assessment*, 2003, 9(5), 1145–1154.

27. North, D. Warner; Kamal M. Abdo; Janet M. Benson; Alan R. Dahl; John B. Morris; Roger Renni and Hanspeter Witschi. "A review of whole animal bioassays of the carcinogenic potential of naphthalene." *Regulatory Toxicology and Pharmacology*, 2008, 51(2(1)), 6–14.

28. Obama, Barack. "Scientific Integrity." *Federal Register*, 2009, 74(46), 10671–10672.

29. Office of Management and Budget. "Current Regulatory Issues in Risk Assessment and Risk Management," *Regulatory Program of the United States, April 1, 1990—March 31, 1991*. Washington, DC: Office of Management and Budget, 1990, 13–26.

30. ————. "Final Information Quality Bulletin for Peer Review." *Federal Register*, 2005, 70(10), 2664–2667.

31. ————. "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Notice; Republication." *Federal Register*, 2002, 67(36), 8452–8460.

32. ————. "Proposed Bulletin on Peer Review and Information Quality." *Federal Register*, 2003, 68, 54023–54029.

33. Phalen, Robert F. "Written Testimony Before the U.S. House of Representatives, Committee on Science, Space, and Technology, Subcommittee on Energy and the Environment, Hearing on 'Quality Science for Quality Air': *The CASAC–PM Committee—Setting Air Quality Standards*," 2011.

34. Price, Paul S. and Michael A. Jayjock. "Available data on naphthalene exposures: Strengths and limitations." *Regulatory Toxicology and Pharmacology*, 2008, 51(2(1)), 15–21.

35. Stark, Andrew. *Conflict of Interest in American Life*. Cambridge, Mass.: Harvard Universitry Press, 2000.

36. The National Academies. "Policy on Committee Composition and Balance and Conflict of Interest," The National Academies, 2003.

37. Thurston, George D. "Written Testimony Before the U.S. House of Representatives, Committee on Science, Space, and Technology, Subcommittee on Energy and the Environment, Hearing on 'Quality Science for Quality Air': RE: *The Science of Air Pollution Health Effects and The Role of CASAC in EPA Standard Setting*," 2011.

38. U.S. Environmental Protection Agency. "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency (EPA/260R-02-008)," 2002.

39. ————. "Peer Review Handbook (1st Ed.)," Washington, D.C.: U.S. Environmental Protection Agency Science Policy Council, 1988.

40. ————. "Peer Review Handbook (2d Ed.)," Washington, D.C.: U.S. Environmental Protection Agency Science Policy Council, 2000.

41. ————. "Peer Review Handbook (3rd Ed.)," Washington, D.C.: U.S. Environmental Protection Agency Science Policy Council, 2006.

42. U.S. Environmental Protection Agency Office of the Science Advisor. "An Examination of EPA Risk Assessment Principles and Practices; Staff Paper, EPA/100/B–04/001," 2004.

Chairman HARRIS. Thank you very much.

I now recognize our fifth witness, Dr. Jerald Schnoor of the University of Iowa, Department of Civil and Environmental Engineering.

STATEMENT OF DR. JERALD SCHNOOR,
ALLEN S. HENRY CHAIR IN ENGINEERING,
DEPARTMENT OF CIVIL AND ENVIRONMENTAL ENGINEERING,
UNIVERSITY OF IOWA

Dr. SCHNOOR. Good morning, Chairman Harris, Ranking Member Miller, distinguished Committee Members. Thank you for the chance to testify before the Subcommittee. I am Jerry Schnoor, Professor of Civil and Environmental Engineering at the University of Iowa. My views are my own today, and I have had the pleasure of serving on a number of committees concerning science at EPA, and I come to you with the shared interest in fostering quality science.

But what constitutes quality science? EPA's mission is to protect human health and the environment from detrimental effects of pollution and other hazards. Their science should be relative to the mission. It should be of high quality and high priority, and it should be reviewed by qualified scientists and engineers constantly. Such high-quality science enables excellent policy decisions to be made by decision makers including Congress, yourselves. In addition, EPA science should help in identifying future and emerging environmental issues. I can testify that the EPA and ORD offer world-class science in a number of areas, including especially air quality modeling, monitoring, and development of emission databases.

Improvements in air quality over the past 40 years are remarkable and a testament to the good science at EPA. Please see figure 1. In the top panel here, increasing population and consumption as measured by gross domestic product, the vehicle miles traveled in America, and energy consumption are drivers. They serve to elevate the emissions in the United States. If one wants to keep up with the ever-increasing pollution from these drivers, it requires increasingly stringent regulations just to maintain the status quo. For the most part, U.S. greenhouse gas emissions—that is CO_2 emissions on the slide—have mirrored the increasing U.S. population, which continues to grow at about one percent per year in figure 1. Notice all three lines in the middle are in lockstep.

But the surprising news from figure 1 is that in the bottom panel, six aggregate air pollutants have been reduced by 41 percent over the past 18-year period. This illustrates a tremendous success story, which constitutes lives saved, better respiratory health for Americans, and billions of dollars in medical costs avoided, not to mention clearer, purer air.

The United States achieved these results by virtue of steadfast EPA adopting new rules and enforcing the Clean Air Act and its amendments. The Clean Air Act is the most expensive legislation

to enforce in the entire U.S. Code, but it has a 30:1 benefit-to-cost ratio still. It has saved thousands of lives and will result in the creation of 1.5 million new jobs over the next five years for the ambient air quality standards alone.

The Office of Research and Development provides a significant portion of scientific research at EPA. In 2011, ORD, as we have heard, realigned their programs from 13 to six, shown on this slide. The realignment was in concert with peer review provided over the past years by both the Science Advisory Board and the Board of Scientific Counselors. Motivation for this consolidation and realignment of programs reflects an emphasis on integrated transdisciplinary research, multipollutant exposures, and sustainability. These are not new programs but rather they represent a new way of thinking within ORD, and I believe considerable synergies may be realized in combining research into the four programmatic areas shown on the right-hand side of the slide and the two smaller programs in Homeland Security and human health risk assessment, also on the right.

As a member of EPA Science Advisory Board and several NRC committees concerned with EPA research, I can assure you that EPA is transparent and heavily peer reviewed already. The entire scientific process from major reports to published research journal articles, from their labs, centers, and divisions to the proposed regulations, all are reviewed by SAB, BOSC, CASAC and other entities. If anything, I would say the scrutiny and accountability of EPA has increased in recent years, based on my own experience serving on those committees.

Thank you very much for the chance to testify.

[The prepared statement of Dr. Schnoor follows:]

PREPARED STATEMENT OF DR. JERALD SCHNOOR,
ALLEN S. HENRY CHAIR IN ENGINEERING,
DEPARTMENT OF CIVIL AND ENVIRONMENTAL ENGINEERING,
UNIVERSITY OF IOWA

Good morning, Chairman Harris, Ranking Member Miller, Distinguished Committee Members, ladies and gentleman. Thank you for the chance to testify before the Subcommittee. I am Jerald Schnoor, Professor of Civil and Environmental Engineering at the University of Iowa and Co-Director of the Center for Global and Regional Environmental Research. I am also Editor-in-Chief of the American Chemical Society journal, *Environmental Science and Technology*, a leading journal in environmental science and engineering. I have had the good fortune to teach and perform research in the environmental area for over 35 years. During that time, I served as the Chair of the Board of Scientific Counselors for EPA Office of Research and Development (ORD) from 2000–2004, and more recently as a member of the Science Advisory Board (SAB) to EPA. I also am a member of the National Academy of Engineering and, as such, have served on a number of National Research Council committees of the National Academies, including one which I am chairing now on science for EPA's future. So I come to you with shared interest in fostering quality science at EPA, and I have organized my testimony in response to the questions posed to me in the invitation letter from Chairman Harris dated January 25, 2012.

What constitutes quality science to support EPA's mission? EPA's mission is to protect human health and the environment from detrimental effects of pollution and other hazards. Thus, EPA's science should be relevant to its mission; it should be of high quality and high priority; and it should be reviewed by qualified scientists and engineers. Such high-quality science enables excellent policy judgments to be made by decision makers. In addition, EPA science should help to identify future and emerging environmental issues.

One recent example which illustrates how quality science can help to inform policy even in a time of crisis involved the Macondo oil spill on April 20, 2010, and the subsequent release of almost 200 million gallons of oil and addition of two million gallons of dispersant to the Gulf of Mexico. Shortly after the accident occurred, EPA was asked about the toxicity of the dispersant that was chosen to break up the oil plume. The toxicological data on dispersants at the time were sparse, but EPA-ORD rapidly engaged in high-throughput testing on eight commercial dispersants at the National Center for Computational Toxicology in the EPA Lab at Research Triangle Park, North Carolina. EPA scientists learned quickly that Corexit 9500, the dispersant used, was comparable or relatively less toxic than other alternative products. In fact, EPA scientists performed the research, wrote and submitted a scientific journal article, and subsequently published the peer-reviewed results on June 30, 2010, only 10 weeks after the original explosion and release of oil (Judson et al., 2010)—a remarkable accomplishment. Those events point to another characteristic of quality science—it should be timely.

EPA should provide high-quality science to inform regulatory decisions. As a research engineer and editor, I can testify that the Office of Research and Development offers world-class science in a number of areas including air quality monitoring, modeling, and development of emissions databases. Improvements in air quality that the U.S. has achieved over the past 40 years are a testament to the good science at EPA. Let's consider air quality in recent decades in the U.S. as a case study for sound science to improve human health and the environment.

Increasing population and consumption are "drivers" serving to elevate emissions both in the U.S. and globally. If one wants to "keep up" with ever-increasing pollution from these drivers, it requires increasingly stringent regulations just to maintain the status quo. For the most part, U.S. greenhouse gas emissions (CO_2-equivalents) have mirrored the increasing population which continues to grow at about one percent per year. Figure 1 shows the lock-step of increasing CO_2 emissions, population, and energy consumption in the U.S. since 1990. They track each other closely, and increasing population and energy consumption result in greater CO_2 emissions. Note that CO_2 emissions have not increased nearly as rapidly as the Gross Domestic Product (GDP), which indicates improved efficiency in a changing economy. Also, the trend in the transportation sector, responsible for approximately one-quarter of all greenhouse gases (GHGs), shows that Americans drove many more miles during this period. Vehicle miles traveled increased 36% from 1990–2008, but the rate of release of greenhouse gas emissions due to transportation has been much less, especially in recent years.

The surprising news from Figure 1 is that six aggregate air pollutants have been reduced by 41% over the 18-year period. This illustrates a tremendous success story which constitutes lives saved, better respiratory health for millions, and billions of dollars in medical costs avoided, not to mention cleaner/purer air. The U.S. achieved these results by virtue of a steadfast EPA adopting new rules and enforcing the Clean Air Act and its amendments. The Clean Air Act is the most expensive legislation to enforce in the entire U.S. code, but it has a highly positive benefit-to-cost ratio and has resulted in lower morbidity and mortality due to lung and cardiovascular disease, and the creation of many jobs by achieving and abiding by the new standards (CERES, 2010). CERES, an organization that articulates the views of major American corporations on their social responsibilities, recently estimated that enforcement of the National Ambient Air Quality Standards alone will result in the creation of 1.5 million jobs over the next five years. The country needs clean energy and clean air as well as high-paying jobs, and the former can augment the latter. In March 2011, EPA issued The Benefits and Costs of the Clean Air Act from 1990–2020. According to this study, the direct benefits from the 1990 Clean Air Act Amendments are estimated to be almost $2 trillion for the year 2020, exceeding costs by a factor of more than 30:1.

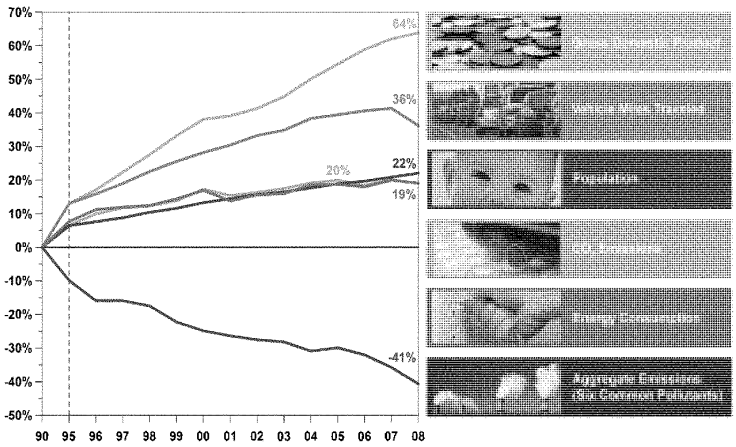


Figure 1. Gross trends in aggregate emissions, carbon dioxide emissions, and their drivers (GDP, VMT, population, and energy consumption) since 1990 in the U.S. (Source: U.S. Environmental Protection Agency, Office of Research and Development, Strategic Plan, 2011)

From Figure 2, one can see the large decline in specific emissions of NO_2 (30 %), Volatile Organic Chemicals (VOC, 53%), carbon monoxide (CO, 54%), sulfur dioxide (SO_2, 55%), and particulate matter less than 10 microns (PM_2, 65%) since the inception of EPA in 1970, and the implementation and enforcement of the Clean Air Act and its Amendments (1967, 1976, 1990). Despite a doubling of the U.S. GDP during this period (and large increases in vehicle miles traveled, population, energy consumption, and CO_2 emissions), regulation of the transportation and industrial sectors has allowed a decline in emissions of air pollutants. Note, however, that the majority of emission reductions from 1970–2005 in Figure 2 occurred prior to 1995 (with the exception of NO_2), illustrating that the rate of improvements have slowed.

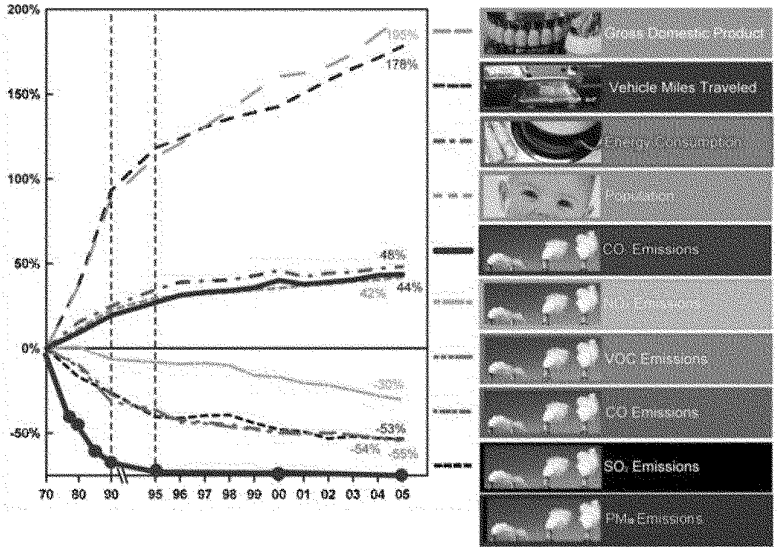


Figure 2. Detailed trends in specific pollutants and drivers since the inception of EPA in 1970. (Source: U.S. Environmental Protection Agency, Office of Research and Development, Strategic Plan, 2011)

Sometimes, there is no single entity or agency that is sufficiently interested, capable, or funded to perform research necessary to protect human health and the environment from pollution. Many times, it is advantageous to form partnerships to combine expertise and resources. A case in point is science to understand the emissions, fate, and effects of fine particulate matter (PM_2) in the 1990s. EPA partnered with the National Institute of Environmental Health Sciences (NIEHS) and the Electric Power Research Institute (EPRI) to fund this seminal research. The famous Harvard Six Cities Study (Dockery et al., 1993) found evidence that not only lung cancer mortality was elevated when fine particles were prevalent in the air of U.S. cities, but cardiopulmonary disease also increased. However, the etiology of the disease, the cause of cardiopulmonary mortality, was unknown. How could fine particles cause disease, let alone death by heart attack or stroke? So it must have been with some trepidation that EPA began to develop regulations in 1996 to regulate fine particulate matter less than 2.5 microns in diameter (PM_2) in order to protect the public health.

Today scientists have a much better idea of how fine particles can kill. In 2000, a reanalysis of the Harvard Six Cities Study was reported by the Health Effects Institute (HEI) and, in 2004, research was completed that validated the initial morbidity results (Krewski et al., 2004). An extended follow-up study by Francine Laden and colleagues was published in 2006 (Laden et al., 2006) and a summary of the beneficial effects on life expectancy by Pope et al. (2009). Laden was quoted in a Harvard School of Public Health Press Release at the time:

> "The follow-up study found that an average of three percent fewer people died for every reduction of one microgram per cubic meter in the average levels of PM_2 fine particulate matter, defined as having a diameter of 2.5 microns or less—narrower than the width of a human hair. This decreased death rate is approximate to saving 75,000 people per year in the U.S."

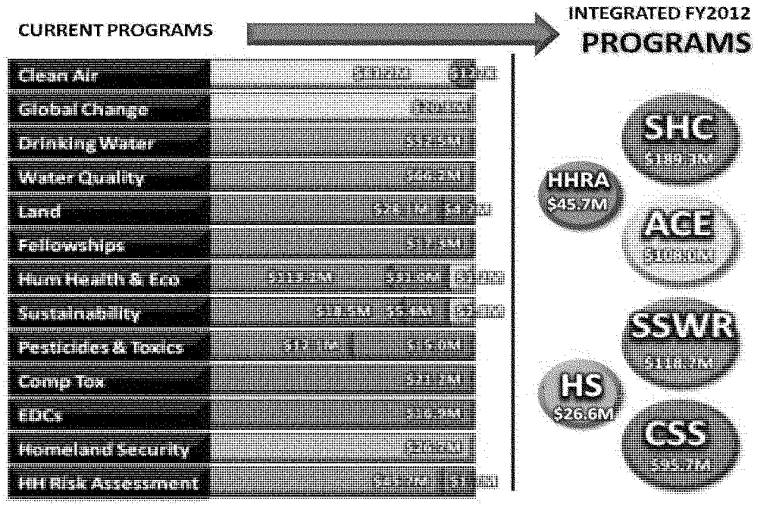
That's an example of quality science performing well—hypotheses are followed by hypothesis testing. Continual challenges in the peer-reviewed literature are followed by subsequent publication and peer review and iterated for further scrutiny of the results until the conclusion emerges and new questions arise. Today EPA funds research at the Rochester PM research Center and the Southern California Particle Center on the health effects of even finer particles, ultrafine particulate matter (UFP). EPA's (2011) Progress Report states, "Ultrafine particulate matter (UFP) is easily transported throughout the body even beyond the cardiopulmonary system. Tissue and cell analysis shows evidence for the translocation of UFP to the liver, kidneys and central nervous system. Surprisingly, there is potential for UFP to cross into the circulatory and lymphoid systems, which could allow the particles to reach sensitive sites, such as the heart, spleen and bone marrow."

How does EPA currently produce quality science? Science is performed by the Office of Research and Development (ORD), by EPA Agency Offices (e.g., Office of Water), through extramural grants and contracts, and through small funding to the EPA Regional Offices and states (NRC, 2000). Science to inform EPA regulations is developed throughout the Agency, conveyed to the Administrator's Office, and utilized accordingly. Of course, funding is provided through the budgetary process and Congress, and oversight is performed by GAO, OMB, and others. EPA employs a strategic planning process to utilize science effectively. ORD seeks to maintain a balance between "problem-driven" research to address immediate policy and regulatory needs and "core" research in the basic environmental sciences, including research to understand future and emerging issues. ORD recently implemented a strategy to support innovation at the bench in ORD laboratories, demonstrate the power of trans-disciplinary research, broaden their network of problem solvers (crowd sourcing), and to showcase the products of such research.

Partnerships are formed within EPA offices and across outside agencies and institutions to perform both intramural and extramural research. Peer review of major products and publications is the system by which objective evaluation and criticism of the science occurs. Increasingly, the National Research Council of the National Academies has played an important role in peer review and advice to the Agency. Considering the importance of air quality for the Agency and the Nation, EPA contracted with NRC to produce a series of reports advising the Agency on airborne particulate matter in the late 1990s and early 2000s. These were viewed as quite helpful at a critical juncture in scientific research to inform rulemaking and policy (NRC, 1998; NRC, 1999). In addition, three FACA committees provide a wide range of important scientific peer review and advice: the Science Advisory Board (SAB), the Board of Scientific Counselors (BOSC), and the Clean Air Scientific Advisory Committee (CASAC). The SAB reviews the President's budget request and provides reviews on various reports which the Agency produces. BOSC provides advice on management of ORD, its multi-year program plans, and reviews of its various centers, laboratories and divisions. Of course, CASAC reviews air pollution reports, rules, and regulations.

The Office of Research and Development (ORD) provides a significant portion of scientific research for the Agency. In 2011, EPA ORD realigned their programs from 13 to six (Figure 3). The realignment was in concert with advice provided in recent years by both the Science Advisory Board (SAB) and the Board of Scientific Counselors (BOSC). Thirteen major programs proved somewhat unwieldy, and the realignment has received positive review from the SAB (SAB, 2011). Motivation for this consolidation and realignment of programs reflects an emphasis on integrated trans-disciplinary research, multi-pollutant exposures, and sustainability. These are not new programs but represent a new way of thinking within ORD. Considerable synergies may be realized in combining research into the four programmatic areas: Air, Climate and Energy; Safe and Sustainable Water Resources (water quality plus drinking water); Sustainable and Healthy Communities; and Chemical Safety for Sustainability; plus two smaller programs in Homeland Security Research and Human Health Risk Assessment (Figure 3).

I believe ORD's realignment is wise, moving EPA research in a new and effective direction. ORD is moving from a *risk management paradigm*, which has guided and influenced research over the past two decades, towards a *sustainability paradigm*. That effort will pay dividends. It is consistent with a public health approach of "preventing disease" rather than a medical approach to "treating disease" after it occurs, and it recognizes that environment and health are an interconnected system. And it follows on early pioneering research which EPA did on Pollution Prevention in the 1990s. Restructuring EPA's research programs, however, is a significant challenge to an established Agency, and ORD must effectively translate research results from these new amalgamated programs into scientifically informed environmental policy.



Key to ORD Program Acronyms

ACE	Air, Climate and Energy Research Program
CSS	Chemical Safety for Sustainability Research Program
HHRA	Human Health Risk Assessment
HSR	Homeland Security Research Program
SHC	Sustainable and Healthy Communities Research Program
SSWR	Safe and Sustainable Water Resources Research Program

Figure 3. Realignment of EPA ORD's many programs into four large programs (ACE, CSS, SHC, and SSWR and two small ones (HHRA and HSR), 2011

What Improvements Are Needed for Future Science at EPA?

With a 41-year history, EPA finds itself in the second decade of the new Millennia with different challenges and variable public support for its mission to protect human health and the environment. EPA has successfully controlled pollution and improved public health and welfare since it was formed in 1970. Success has stemmed largely from establishment and enforcement of its regulatory programs under the Safe Drinking Water Act, the Clean Air Act, FIFRA, Superfund, TSCA, and others. Those successes have been informed by good research, both intramurally and extramurally, within the Agency and outside the Agency by universities, colleges, and partnering agencies/institutions.

But EPA has been successful in reducing pollution mainly at the local scale for single conventional pollutants where the legislative mandate was strong. Now, our environmental problems are at larger scale (regional to global) and involve aspects without solid legislative authority (e.g., agricultural runoff, land use and climate change, and choice of energy systems). Some factors driving these new challenges to human health and the environment in the U.S. include the following:

- Population growth and geographic shifts towards the South, West, and the coasts;
- Land use change (urban sprawl, coastal development, agricultural practices);

- Energy choices (biofuels, shale gas by hydraulic fracturing, deep offshore oil, oil sands, coal bed methane, concentrated solar power, wind energy);
- Increased consumption and technological changes (globalization of trade and invasive species, e-waste and complexity of new electronic devices from 11 to 60 elements of the periodic table, new plastics and flame retardants, endocrine disrupting chemicals);
- Climate change (increased precipitation intensity, changing precipitation patterns, increasing floods, droughts, forest fires, tornadoes, hurricanes).

These factors have resulted in a new suite of emerging environmental challenges for EPA:

- Air quality deterioration due to warmer, moister climate;
- Agricultural runoff and nutrient quality criteria from climate change and land use choices;
- Urban stormwater and by-pass exacerbated by sprawl and storm severity;
- Terrestrial ecosystem degradation (loss of species such as birds, bees, butterflies, bats);
- Coastal waters ecosystems degradation (harmful algal blooms, red tides, and hypoxia).

EPA's science in the future will require a new and innovative approach to investigating problems of broader scope where legislative mandates are not strong. Land use change, energy choices, coastal development, and climate change represent "wicked" problems of the future for which quality science is needed to chart the path forward.

EPA must employ the most modern emerging technologies and tools to address these problems. A nimbleness and adaptability will be required to identify new environmental threats. Partnering and networking with other agencies, other countries, and U.S. citizenry to fashion creative innovative solutions to thorny problems must become the norm. Every form of efficiency and innovation will be necessary. Certainly, a science budget commensurate to these pressing problems and sufficient to support policy decisions and regulatory actions will be needed to protect human health and the environment in the future. This includes better use of social, behavioral, and decision scientists who understand how to develop alternative approaches for desired environmental behaviors, rather than end-of-pipe command-and-control regulations. Sometimes there is no alternative to direct control and regulation, but EPA must think more creatively and seek market and behavioral solutions when they present themselves.

Given the planned shift toward multi-pollutant cumulative risk assessment and the backlog of ten thousand chemicals that need to be assessed, there is a need to invest in modernizing the human risk assessment approach to move beyond the one-pollutant-at-a-time framework. ORD should develop a clear plan for how the outputs of the Chemical Safety for Sustainability (CSS) program (e.g., Tox 21, NexGen) will be used by the Human Health Risk Assessment program.The Safe and Sustainable Water Resources SSWR program will need to increase their focus on viewing water and wastewater holistically as an integral part of the overall water cycle. Wastewater is not a "waste," but rather a resource from which we will recover water, nutrients, and energy for reuse, and it will be used to make communities more socially, economically, and environmentally sustainable. This is in concert with EPA's changing role from not only a regulatory agency, but to one that promotes sustainable and healthy communities.Lastly, EPA should assume leadership in the social, behavioral, and decision sciences more broadly as an explicit research enterprise and cross-cutting strategy. Scientific research in these areas is inexpensive relative to the costs involved in much of the physical and biological sciences. Relatively modest investments in this cross-cutting domain could have large future benefits to protect human health and the environment (SAB, 2011).

References

1. CERES (2011). New Jobs Cleaner Air: Employment Effects under Planned Changes to the EPA's Air Pollution Rules, University of Massachusetts, Political Economy Research Institute 9 James Heintz, Heidi Garrett-Peltier, Ben Zippere), *www.ceres.org/epajobsreport*.

2. Dockery, D.W. et al. (1993). An association between air pollution and mortality in six U.S. cities, *The New England Journal of Medicine* 329 (24), 1753–1759.

Environmental Protection Agency (2011). Science and Research at the U.S. Environmental Protection Agency—EPA Progress Report 2010, EPA/600/R–011/067, Of-

fice of Research and Development, U.S. Environmental Protection Agency, Washington, D.C., 79 pp.

Judson, RS, et al. (2010). Analysis of eight oil spill dispersants using rapid, in vitro tests for endocrine and other biological activity, *Environ. Sci. Technol*. 44, 5979–5985.

Krewski, D. et al. (2004). Validation of the Harvard Six Cities Study of particulate air pollution and mortality, *New England Journal of Medicine* 350 (2), 198–199.

Laden, F., Schwartz, J., Speizer, F.E., Dockery, D.W. (2006). Reduction in fine particulate air pollution and mortality, *Am J Respir Crit Care Med* 173, 667–672.

National Research Council (1998). Research Priorities for Airborne Particulate Matter I. Immediate Priorities and a Long-Range Research Portfolio, National Academy Press, National Academy of Sciences, 195 pp.

National Research Council (1999). Research Priorities for Airborne Particulate Matter II. Evaluating Research Progress and Updating the Portfolio, National Academy Press, National Academy of Sciences, 111 pp.

National Research Council (2000). Strengthening Science at the U.S. Environmental Protection Agency—Research Management and Peer-Review Practices, National Academy Press, National Academy of Sciences, 159 pp.

Pope, A., Ezzati, M., Dockery, D.W. (2009). Fine-particulate air pollution and life expectancy in the United States, *New England Journal of Medicine* 360, 376.

SAB Science Advisory Board (2011). Science Advisory Board Comments on the President's Requested FY 2012 Research Budget, EPA-SAB-11-007, U.S. Environmental Protection Agency, Washington, D.C., 30 pp.

Chairman HARRIS. Thank you very much.

And now our final witness, Dr. S. Stanley Young, the Assistant Director for Bioinformatics at the National Institute of Statistical Sciences.

STATEMENT OF DR. S. STANLEY YOUNG, ASSISTANT DIRECTOR FOR BIOINFORMATICS, NATIONAL INSTITUTE OF STATISTICAL SCIENCES

Dr. YOUNG. Mr. Chairman, Mr. Harris and others, today I am here to speak to making data sets used in papers supporting regulation by the APA publicly available.

It is just good science to have data used in papers public. A claim can be made. Is it plausible? If the data is not available, then the claim is effectively "trust me" science. You might think a claim is made in a peer reviewed journal. Surely that makes it right. Peer review only says that the work meets the standards of the discipline, and on the face of it, the claims are plausible. Scientists doing peer review essentially never ask for the data set. They look for obvious things to correct, agree or not with the claims, agree or not that the claims make some sense.

How often do claims prove false or dramatically less pronounced in the original paper? Ioannidis in 2005 showed that for medical observational studies, claims fail about 80 percent of the time. I have kept an informal count of claims coming from medical observational studies and then tested in randomized clinical trials. Over 90 percent of the claims have failed to replicate. Yes, 90 percent failure rate. I refer you to a recent paper that covers these findings, Karr and Young, 2011.

There are a number of technical systems and reasons for the high failure rate, which I will not deal with here. I will say that the work of Congress and the work of regulatory agencies often depend on valid science. With the best of intentions and incorrect scientific claims, you can make spectacularly bad decisions.

To give a historical medical example, two very large observational studies made the claim that vitamin E will protect against heart attacks. Several large, randomized clinical trials did not support those claims. Hundreds of millions of dollars were spent on the randomized clinical trials.

My goal here is to suggest several things that can be done to improve the situation. Any regulation that depends on epidemiology studies, for example, formaldehyde, should make data sets public. The ACS CPC II data set that is being relied on for air pollution regulations should be public.

It makes sense to fund the data generation and the data analysis separately. One group collects and stages the data and posts it. Separate groups of scientists can be funded to analyze the data. Other interested scientists can analyze the data. Scientists can become vested in the claims they derive from a data set. One group of scientists should not own a data set.

Making efficient running of science is a good way forward. Science is much more efficient if the scientists have access to the data used to make claims. One scientist can make a claim and another can say let's examine the data and see if the claim is supported. Maybe there is a problem. For example, a Duke University study that led to clinical trials was discovered to have data-staging errors, just the handling of the data.

Perhaps the scientific analysis strategy is flawed. I examined a data set where a claim was made that eating breakfast cereal would make boy babies more likely. Examination of the data set showed the claim was a result of a flawed statistical analysis strategy. Evidence from medical observational studies indicates that claims most often fail to replicate. Environmental epidemiology studies are just as subject to error.

On publication of a paper where research is used to—is funded by the EPA, the data should be made public. When the EPA proposes a regulation based on science, it should name the papers it is depending on and should make the data sets used in those papers publicly available. The agency should want to move forward based on good science. Congress should want the EPA regulations based on good science. The EPA would be more efficient if the entire scientific process is utilized. Congress would then depend not only on the EPA but on the normal operating of science. Claims are more likely to be valid and resulting policy sensible. Let normal science help in the vetting process. Make the data sets available.

[The prepared statement of Dr. Young follows:]

PREPARED STATEMENT OF DR. S. STANLEY YOUNG,
ASSISTANT DIRECTOR FOR BIOINFORMATICS,
NATIONAL INSTITUTE OF STATISTICAL SCIENCES

I am Dr. S. Stanley Young.

I am the Assistant Director for Bioinformatics at the National Institute of Statistical Sciences, NISS. NISS is a not-for-profit, non-governmental statistics organization. NISS' mission is to identify, catalyze, and foster high-impact, cross-disciplinary research involving the statistical sciences. I am also the CEO of Omicsoft Corporation, a company that designs software.

I graduated from North Carolina State University, BS, MES and a Ph.D. in statistics and genetics.

I've worked in the pharmaceutical industry on all phases of pre-clinical research, first at Eli Lilly and then at GlaxoSmithKline. I've authored or co-authored over 60 papers and book chapters, including six "best paper" awards. I co-authored a highly cited book, *Resampling-Based Multiple Testing*, which deals with false positives, among other things. I have three issued patents. I conduct research in the area of data mining.

I am a Fellow of the American Statistical Association and the American Association for the Advancement of Science. I am an adjunct professor of statistics at North Carolina State University, the University of Waterloo, and the University of British Columbia.

Today I am here to speak to making data sets used in papers supporting regulation by the EPA publicly available. It is just good science to have data used in papers public. A claim may be made. Is it plausible? If the data is not available, then the claim is effectively "trust me" science.

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There are a number of technical and systems reasons for the high failure rate, which I will not deal with here. I will say that the work of Congress and the work of regulatory agencies often depends on valid science. With the best of intentions and incorrect scientific claims, you can make spectacularly bad decisions. To give a historical medical example, two very large observational studies made the claim that Vitamin E will protect against heart attacks.

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It makes sense to separately fund data generation and data analysis separately. One group collects and stages the data and posts it. Separate groups of scientists can be funded to analyze the data. Interested scientists can analyze the data. Scientists can become vested in the claims they derive from a data set. One group of scientists should not "own" a data set.

Making efficient the running of science is a good way forward. Science is much more efficient if scientists have access to the data used to make claims. One scientist can make a claim and another can say, let's examine the data and see if the claim is supported. Maybe there is a problem. For example, a Duke University study that lead to clinical trials was discovered to have data staging errors. Perhaps, the statistical analysis strategy is flawed. I examined a data set where a claim was made that eating breakfast cereal would make a boy baby more likely. Examination of the data showed the claim was the result of a flawed statistical analysis strategy. Evidence from medical observational studies indicates that claims most often fail to replicate. Environmental epidemiology studies are just as subject to error.

On publication of a paper where research is funded by the EPA, the data should be made public. When the EPA proposes a regulation based on science, it should name the papers it is depending on, and it should make data sets used in those papers publicly available. The agency should want to move forward based on good science. Congress should want the EPA regulations based on good science. The EPA would be more efficient if the entire scientific process is utilized. Congress would then depend not only on the EPA but the normal operating of science. Claims are more likely to be valid and the resulting policy sensible. Let normal science help in the vetting process. Make the data available.

Chairman HARRIS. Thank you very much for your testimony, and now we will begin the round of questions. I will recognize myself for the first five minutes. And again, I want to thank you all for taking the time to come here and advise the Committee on such an important topic.

It is kind of interesting that sandwiched between the first hearing and this hearing, we had the hearing Wednesday about the Pavillion, Wyoming, study, which of course the ORD participated in, and one of the things that we discovered at the hearing was that in fact data was withheld until the night before the hearing, certainly not an example of the transparency I think some of you have called for.

Let me just ask, Dr. Swackhamer, the Health Effects Institute has recently conducted retrospective accountability research in specific instances to see if regulatory decisions actually produce predicted health outcomes, and Doctor, you understand that we get testimony such as, you know, gee, if we just passed this rule or regulation, you will have 200,000 less asthma cases and, you know, 600 million less cardiac deaths and all the rest. My understanding is that EPA devotes a very small portion of their R&D budget toward this kind of research, and my interest is piqued because every single time we have had an air pollution hearing, we have been promised that asthma incidence would go down, and I am a physician. You know what happened to asthma incidence in the last 30 years, that same graph that shows that wonderful decline in air pollution over the last 30 years? I suggest, Dr. Schnoor, that perhaps you should graph the incidence of asthma. It has gone up over 30 years. What is the EPA doing in their R&D budget to look at whether or not these health benefits that are claimed actually come to pass in the magnitude that they are claimed? Because, again, we have testimony that you have a 30:1 benefit ratio of doing these. Well, my suggestion is, great, let us spend half a billion dollars and we can solve our federal debt if it is a 30:1 ratio. That would be quite simple. As a scientist, I have to believe that is an oversimplification and, I suspect, an exaggeration. If we just look at asthma as an index case, could you tell me whether that kind of backward-looking evaluation would improve agency decision making?

Dr. SWACKHAMER. What I can tell you, Mr. Chairman, is that I am not in charge of EPA's budget so I don't really know how they are spending their budget in terms of these kinds of studies.

Chairman HARRIS. Would you recommend the Science Advisory Board, since the Science Advisory Board should recommend how science is used and they use science—see, that is the thing, and this is the crux of the matter. The policymakers, as has been pointed out by the panel, point to science as a justification and claimed scientific studies that claim hundreds of thousands of less asthma cases, which appear not to have occurred.

Dr. SWACKHAMER. Mr. Chairman, one of the things that we are recommending is integrating science into decision making, and what that means—that is kind of a fancy phrase, but what it means is that there is a process that both the National Academy has recommended, and now the Science Advisory Board in a draft report is recommending, and part of that process—you know, you look at a diagram—is to first formulate the problem, then do the science necessary to address the problem, and then complete the loop that you are talking about and looking at assessing whether the fix was appropriate and making adjustments as you go.

Chairman HARRIS. Well, thank you.

Dr. SWACKHAMER. So we are recommending to do exactly what you are asking.

Chairman HARRIS. Dr. Belzer, you have criticized the EPA's retrospective look at the overall cost of the Clean Air Act, again, you know, this 30:1 benefit ratio. Is there a better way to assess regulatory outcomes to maximize what are finite EPA resources?

Dr. BELZER. Well, certainly, these estimates are done ex ante. The estimates are done before the jury comes in. It certainly would helpful to have retrospective analysis. I think that is a very useful thing. I think as a general rule, agencies don't like to do it broadly. I think the NHTSA may be a good exception to that. They are a bunch of engineers. They really like doing that sort of thing.

The larger problem with this set of rules is that it is EPA that is charged by Congress with doing the retrospective review of its own work and so I think——

Chairman HARRIS. I understand the implicit conflict of interest when you are charging with looking back at whether or not you have been effective.

Dr. BELZER. I certainly have always been effective.

Chairman HARRIS. I understand that.

Mr. Walls, last year the EPA announced numerous changes to their IRIS process to respond to criticism from NAS and GAO including the creation of a standing IRIS advisory panel. Is the problem fixed?

Mr. WALLS. Mr. Chairman, we think that the announcements from EPA are a very good step in the right direction, but I think we are in a situation where we really have to trust but verify. We have to ascertain that these changes are in fact addressing the problems that have been identified. I think there are still some concerns, for example, of how this new SAB committee that IRIS has established is going to work. I have every confidence that Dr. Swackhamer and her colleagues are committed to doing a great review of those assessments but I question whether or not the process is really independent. I think we have heard that EPA staff has kind of unfettered access to the reviewers. You know, that contrasts sharply with peer review done by the National Academy. So we are encouraged. We will wait to see more.

Chairman HARRIS. Thank you very much.

I recognize the Ranking Member.

Mr. MILLER. Thank you, Mr. Chairman.

Since there have been more than 30 years since ERDDAA was reauthorized, or authorized, the scientific community has had some time to think about it, and in preparing for reauthorizing ERDDAA, there have been several suggestions that would improve or suggestions for how to improve EPA research, to make it more efficient, transparent, and even more credible. One that we have heard repeatedly is there could be more integrated science within the EPA, and the National Academy of Sciences has called for a top science official. They say the lack of a top science official is a formula for weak scientific performance in the agency, and they suggest that Congress create a new position of Deputy Administrator for Science and Technology with responsibility for coordinating and overseeing agencywide scientific policy, peer review quality assurance.

Dr. Swackhamer and everyone, what is your opinion, what is SAB's opinion on the advantages or disadvantages of creating a position like that? Would that make the head of ORD—creating a deputy-level position make the head of ORD an obsolete position? Or is it realistic to think that one person, one position, would be able to handle the responsibility for the large test of overseeing all of EPA's research so that we would need both a deputy and the head of ORD?

Dr. SWACKHAMER. Mr. Chairman, Mr. Miller, the Science Advisory Board has a panel right now that is drafting a report on science integration at the agency, and one of the things they have discussed is the need for scientific leadership across the agency, not just ORD, which obviously has a science leader, but to improve the leadership across the entire agency linking the science enterprise both at the program offices and the regional offices with the entire agency to integrate across the whole agency. So we recognize the need for improved integrated leadership and coordination across the agency. We have not made a stand or made a statement or come to a conclusion about how to implement that in terms of whether it is a deputy or not.

Mr. GREENBAUM. Just to reiterate the importance of this, understanding that more than two-thirds of all scientists at EPA do not work at ORD. They work in other parts of the program, and one of the big challenges is that they are all working at that place where they are both creating some science but they are then involved in the interpretation of that science. So making sure through some enhanced science leadership, there is currently a chief science advisor, whether that is the right mechanism or some other one, that there are consistent procedures for transparency, for peer review and various other things across the agency is an important factor. Whether or not the full deputy is the right approach, as you know, there are plusses and minuses to creating a new senior position of that type.

Mr. MILLER. There may be more opinion than there is time, so could you state an opinion succinctly, Dr. Belzer?

Dr. BELZER. I just want to comment that this idea has come up many times in the past. One of the things to keep in mind is that for a Deputy Administrator for Science to be effective, the deputy would have to have a very large staff and that staff would have to be independent of all the program offices and independent of ORD. So when you think about this as an idea, think about what it takes to fully flesh it out so that it actually has the capacity to be effective in an agency with, what, 14,000 employees or something like that.

Mr. MILLER. Dr. Schnoor, did you have an opinion?

Dr. SCHNOOR. Very quickly. I would agree with much of what has been said. I am not positive that it has got to be a deputy administrator level, but the need for coordination of science throughout EPA, even down at the regional, I agree with wholeheartedly, and that needs to be better coordinated.

Mr. MILLER. Dr. Young?

Dr. YOUNG. Just a quick comment. We can talk about top down or we can talk about bottom up. Top down, you have a director.

Bottom up, if you make all the data sets available, good decisions will start at the bottom and the top will take care of itself.

Mr. MILLER. Anyone else? Okay. I will yield back 25 seconds.

Chairman HARRIS. Thank you very much, and the gentleman from California to my left is going to defer to the gentleman from California on my right while he prepares his questions. Anyway, I recognize Mr. McNerney from California for five minutes.

Mr. MCNERNEY. Thank you, Mr. Chairman. I thank my friend from California for letting me go first.

I also want to thank the Chairman and the Majority Staff for making what appears to be a good effort at sort of a balanced approach to this. It is a complicated subject. The EPA is a big organization, a lot of science going on, a lot of money being spent, and we all want to make sure that it is done right, that the money is effective, we don't make regulations that cause more problems than they solve, and so I really welcome the witnesses and the hearing.

My first question goes to Dr. Belzer. In your testimony, you stated and made a point that the EPA should be free from politicization. I think everybody would agree with that. There should be some policing of the agency to make sure there is a good boundary between science and policy. My question to you is, what about industry? Should industry have the same standards that draws a boundary between science and policy, or should industry be able to just run roughshod over policy and any decisions that are being made here in Washington?

Dr. BELZER. I don't see any reason why there would be any difference with respect to science. The issue—I don't think industry makes regulatory decisions. It is a little bit different for government. It has certain responsibilities that exceed those of all the interest groups that feed into it. Transparency in science and effective peer review are probably the very best tools available for dealing with problems like scientization or politicization. I think that that is the best that we can do and it should be applied to everyone. I like the idea of having more and more competition, more and more people playing in this and participating and doing research, and let the best research win.

Mr. MCNERNEY. Well, I think you said the right word, the transparency. If we could make sure that industry is transparent in their impact on policy, then I think we would be a lot better off.

Mr. Greenbaum, thank you for your input this morning. In your testimony, one of the things that was disturbing is that you mentioned scientists are hesitant about getting involved in the controversial policies with the EPA or involving EPA reviewing. Could you give us some clue as to how we could better that situation?

Mr. GREENBAUM. Yeah, and I tried to make it very clear. I know that the Science Advisory Board goes out of its way to try and recruit a wide range of scientists, but if you do look at the rosters of people who are willing, for example, to join panels at the National Research Council and the group that is at EPA, is not a complete overlap. There are people who are hesitant to become involved because of the public scrutiny that comes in, the criticism, sometimes unfair, that comes in, and the time involved, and I think you need to reach out. It is particularly important to reach out beyond the immediate people, for example, who are only doing work

in environment and health. An example of that is statisticians. There are a number of very good statisticians who have worked in the medical arena. We recruit some of those. We are able to do that, and sometimes because of who we are, we are able to get those people into the academies, and I think the more you can do that, the better off you will be because you get fresh perspectives and new ideas. It is not a criticism. I do think that the Science Advisory Board has tried to reach out, but there are scientists who will hesitate to sort of put themselves out of the frying pan and into the fire by going right to work for——

Mr. MCNERNEY. Do you think the peer review process is working in terms of helping the EPA come to decisions?

Mr. GREENBAUM. That is a broad statement, because peer review applies to a lot of what the agency does, and I think it varies across all of the various programs and others. I think there are many cases certainly in the process by which the science is peer reviewed, for example, in the clean air decisions. I think that the science part of that goes extremely well and is done as a model compared to, for example, the way Europe sets similar standards or others. But in other areas, I think there are more questions about exactly how that peer review operates.

Mr. MCNERNEY. Thank you.

Dr. Young, you made some pretty sweeping claims about the peer review process. I have been involved in it, and you say that most peer reviewers don't even ask for data. That is pretty—that is a pretty blanket statement, and I again come to the conclusion from your testimony that you don't think peer review is sufficient. If that is the case, what do you think would be sufficient? And do you follow those practices in your own case? Do you follow what you think would be sufficient?

Dr. YOUNG. I always make my data sets available unless they are controlled by somebody else. I have made lots of data sets available. I am very experienced with the peer review process. I peer review for 10 or 15 different journals and I talk to a wide range of scientists that are peer reviewers. I think my statement is pretty accurate. The peer review of a journal article, if a scientist is very conscientious, he may take a day to look at a paper, he may take only a few hours. There is no way that that person can look at the data. He is trusting that the scientists on the other side did the work in a very legitimate way.

Now, the other thing to say is, the 90 percent of the papers that I have looked at where the things did not hold up, those all came from peer reviewed journals. They came from *JAMA*. They came from the *New England Journal of Medicine*. They came from the best journals on the planet. Peer review does just what I said. It is a quick look at the data. Obvious things are fixed but the data is not looked at, and the evidence is, it doesn't hold up, particularly in the case of observational studies, particularly in the case of epidemiology studies. Ninety percent of the time, the claims do not hold up, and it is not just me. You guys are trusting that those claims are good, and I am saying with a lot of——

Mr. MCNERNEY. So what should be done to replace peer reviews?

Dr. YOUNG. Peer review replacements, I am going in incremental steps. Make the data available. The scientific process is that then

other scientists can look at the data and see if they reach the same conclusions. Don't rely on the peer review system, don't rely on a few experts; rely on the entire scientific process. And if you make the data set available, that will come into play and eventually truth will come out.

Mr. MCNERNEY. May I ask another question, Mr. Chairman?

Chairman HARRIS. We would like to get at least everybody in before we break for votes and then decide. Do you have one quick question?

Mr. MCNERNEY. Well, Dr. Schnoor would like to——

Dr. SCHNOOR. May I just add something to what Dr. Young said?

Chairman HARRIS. Sure, really quickly.

Dr. SCHNOOR. As a journal editor, our policy is, and most journals, that if the data is asked for, we do give it, but I agree with Dr. Young that often it is not asked for, for the reasons that he has expressed.

But I would add one thing that I think is important to the story, and that is that usually an important paper will get eventually reproduced. Somebody will try to do that again, and if it fails, then the literature will change. I tried to represent that in my written testimony.

Chairman HARRIS. Thank you very much. I hope they allow them to come in and try to verify the Pavillion findings.

I now recognize the gentleman from California, Mr. Rohrabacher.

Mr. ROHRABACHER. Thank you very much, Mr. Chairman, and let me just note about the point that was just made, that I think that we should take that very seriously, that all data should be made available, not just conclusions that the people in charge of a project have made about the data. When we see what happened in the Climategate scandal, well, half of it is where we have these scientists talking to each other about how they are going to limit how much other people know about the data they have collected. That is what got everybody angry, and I know there is a group of people in the scientific community that want to just ignore that atrocity, but it is an atrocity when you hear a scientist talking about limiting knowledge, limiting the availability of knowledge to other people. So now on with my questions.

I am concerned about conflict of interest in the scientific community, and especially in terms of the SAB and what we need here, let me just ask, you can have a bias towards certain businesses but you can have also biases towards certain positions. In the academic community, we find these incredible conflicts where some people won't even let someone be hired by their department at a university if they disagree with them, and so we have to consider that if someone is getting, for example, EPA grants in order to prove something, that would suggest that they have perhaps a bias. Let me ask Dr. Swackhamer here on this, does SAB policy make a distinction between the conflict of interest related to receiving federal grants from the EPA, for example, for research and conflicts with private industry? Shouldn't both of them be considered prejudicial, let us say?

Dr. SWACKHAMER. Mr. Chairman, Mr. Rohrabacher, yes, the SAB has a very rigorous process of looking at conflict of interest prior to every activity, so it is not just an annual kind of event. It is be-

fore every single activity we take on. Every member who participates fills in a conflict of interest form and must answer questions, not just related to financial conflict of interest but in terms of impartiality, whether they have made public statements on the topic, whether they have grants related to that topic. So we actually look at the issues, the very issues you have raised. We are actually very sensitive to those issues.

Mr. ROHRABACHER. So someone can receive EPA grants but—in other areas but they cannot serve and exercise authority in areas they have already received EPA grants?

Dr. SWACKHAMER. Well, as an example, what we do is, the SAB does not look at individual EPA projects or individual grants. We look at overall programming. So if an investigator gets an EPA grant and also sits on the Science Advisory Board, if the grant is unrelated to—that specific grant is unrelated to the overall activity that we are reviewing, then that is not considered a conflict. But as an example, I have a long history of EPA funding, and we just recently reviewed the Great Lakes Restoration Initiative study plan, and I recused myself on that particular issue because the GLRI is such a broad program, I felt that I did have a conflict.

Mr. ROHRABACHER. Well, Mr. Walls described in his testimony that sometimes peer reviewers are often overly deferential to the EPA and the EPA staff. After all, especially if they are—if the EPA is giving them a grant for something, but do you think that insisting that EPA staff be present at such meetings has a chilling effect? I will ask that to Mr. Walls.

Mr. WALLS. Yes, Mr. Rohrabacher. We do believe that there needs to be a higher degree of independence for the SAB in conducting these peer reviews. I think there are some practices within peer review in the agency and indeed across the government that suggest some greater links between those who are actually conducting these assessments and the peer reviewers, so we need to have a greater degree of independence.

Mr. ROHRABACHER. And Dr. Schnoor, is that the—okay. Good. You served on the SAB Board of Science Counselors, but around the same time you were very active in various issues. For example, you wrote an article about hydraulic fracturing entitled "Regulate Baby, Regulate," and you also filmed a YouTube video in which you said that all coal-powered electric generation should be shut down. Do you think that someone who is such an advocate as this, doesn't that represent a conflict of interest with making—giving people advice, providing scientific advice for the EPA?

Dr. SCHNOOR. Just one small correction. The issue on coal was no new coal-fired power plants, not to shut down——

Mr. ROHRABACHER. All right. Well, that is still quite an——

Dr. SCHNOOR. It is a strong statement.

Mr. ROHRABACHER. It is still advocating——

Dr. SCHNOOR. It is a strong statement, and those are opinion pieces, and they are labeled as opinion pieces as such, and I do declare them in my activities on the SAB board. I do declare them and sometimes recuse myself from an issue directly involved——

Mr. ROHRABACHER. Well, let us just note that when someone works for an industry, yeah, we have to understand they have a conflict of interest there, but if people, and especially in the aca-

demic world, have made a specific advocacy, that becomes part of their self-interest as well.

Dr. SCHNOOR. It is, and of course, it is out there for everyone to see because it is freely available and published and it is disclosed whenever those——

Mr. ROHRABACHER. As long as the same standard is for industry, that is fine.

Chairman HARRIS. Thank you very much.

The gentleman from New York, Mr. Tonko, is recognized for five minutes.

Mr. TONKO. Thank you, Mr. Chair.

The Subcommittee attempts to explore the areas of transparency, and in keeping in that vein, Dr. Belzer, your CV indicates that you are an independent consultant. Can you indicate for whom you consult?

Dr. BELZER. I am not prepared to reveal the identifies of existing or past clients because they are covered by confidentiality agreements that I am obligated to honor. I am sorry. That is far as I could do on that.

Mr. TONKO. The agreements are confidential or your relationship to them is confidential?

Dr. BELZER. I am not entirely sure——

Mr. TONKO. Well, confidential materials with which you are consulting, to which you are consulting, or the groups themselves, the clients themselves?

Dr. BELZER. I really don't know. I am not sure that I am understanding it clearly enough, because it seems like a fine distinction that is important to you but I don't quite follow it. When I do things that are public or when I put my name on something, a piece of work that I produced, then I disclose who I did it for.

Mr. TONKO. And the Regulatory Checkbook of which you serve as president is described as a nonprofit organization?

Dr. BELZER. It sure is.

Mr. TONKO. Who funds the Regulatory Checkbook?

Dr. BELZER. It is funded by a small number of unfortunately too-small donations. We have done projects in the past and we were able to engineer a large project. I bring an example along. I have done a few things like that. But a large project will take a lot of donors, and those are disclosed. I brought one along. I would be happy to leave it for you. But the work of the project is published in a scholarly journal, and it has got, you know, complete disclosure of every organization that funded the work. So I have done other work here. I have got another thing recently published on the National Toxicology Program, and that is identified who funded it. I have done work for the government of Canada, and that is here as well and, you know, you are welcome to have a copy of that, too.

Mr. TONKO. Dr. Swackhamer and Dr. Schnoor and Mr. Greenbaum, you as a threesome seem to have the most experience on this panel reviewing EPA's science, and each of you has provided helpful suggestions to maintain or improve science at EPA. At the same time, we do hear a lot of criticism of the agency's science routinely. And I would like to present to you—share with you a question and ask for a simple yes or no answer. You can elaborate after your yes or no. With the understanding that individual efforts may

fall short of quality goals and that things can always be improved upon, is the science conducted, in your opinion, by the EPA generally of poor quality?

Dr. SCHNOOR. I would say no, it is of good quality, but it does vary from topic to topic, and that means that there is always room for improvement.

Dr. SWACKHAMER. I believe that the answer to that is no, it is not of poor quality. It is of good quality. At times it is very high quality.

Mr. TONKO. Thank you.

Mr. Greenbaum?

Mr. GREENBAUM. I would agree that the answer is no. I do think that there are cases where it is of—it might almost become poor quality, but I think also the agency has shown its ability to learn from mistakes, for example, in the air quality area it created an entire new database of the latest science on air quality and health which it is using and which is available to everybody who wants to use it to find the latest studies. That is a place where it had been criticized in the past and it is now doing it very well. In fact, it is a leader in the world in that.

Mr. TONKO. Thank you, Mr. Chair. I will yield back.

Chairman HARRIS. We are not going to have to go to vote for about 10 more minutes so we are going to take another five minutes. We have agreed to divide five minutes per side. So let me—I will start and then I will turn it over to Mr. Miller.

Dr. Schnoor, I am going to follow up a little bit about what the Congressman from California here on my left asked about, and that is the—when a scientist veers into personal advocacy, writes an opinion piece called, you know, "Regulate Baby, Regulate," you have to look at—although it is an opinion piece, I mean, I read through it. I thought it was pretty interesting. Well, I thought it was interesting because first of all, I think you were the editor of the journal when you wrote the opinion piece, so that is not just kind of a Tom, Dick and Harry writing an opinion piece, that is the editor of the journal.

Now, I am going to use a phrase, because as a scientist, you have to appreciate, and we brought this out at the hearing two days ago, that a scientist uses words very specifically. Like for instance, if you say "likely" that means then it probably has, you know, more likely than not it occurred. If you say it is the "best supporting evidence," that means it is probably not likely but it is probably the best among a wide variety of alternatives. And by the way, these are terms that were used in the Pavillion report. You say in your opinion piece that for hydro fracturing causing—in addition to causing tap water to burn, you used the word "cause," a very specific scientific word that means there is a cause and effect. You cause it to burn. I looked through the entire literature yesterday and I couldn't find scientific evidence that hydro fracturing caused anybody's tap water to burn. I went back and looked at that case in Colorado, and I am sure you reviewed that before you wrote the word "cause" where in Colorado they tested that water and found that that water that you mentioned that comes in that Gasland film was in fact biogenic, not thermogenic, that in fact there is overwhelming evidence that it was not a result of gas coming from

deeper sources but it was a relative—you understand the science behind it. There is large series—and yet you choose to use the word "cause" as a scientist. Does that mean when you write an opinion piece, you use different words than when you write a science piece? Fill me in on this, because this blurring is a bone of contention on our oversight at the EPA. When a scientist takes work and uses words and then the press office uses slightly different words and then they kind of blend these two and then you dig a little bit, and oh, by the way, we don't want to share the data until the night before the hearing so none of our experts have a chance to look at it before they have a hearing. Call me skeptical. Could you address your use of the word "cause" in that article?

Dr. SCHNOOR. Thank you, Chairman Harris. Yes, I can. First of all, the use of the word was in the context of the Gasland film as having caused the——

Chairman HARRIS. Well, if you pardon me a second, I am looking at the paragraph, and you said—and it is a different paragraph. It says—it implies that hydro fracturing caused tap water—and a home has exploded. Now, I won't even get to the home exploding because I didn't even know about that.

Dr. SCHNOOR. It was in the context of referring to the Gasland film, and also I would like to clarify that, you know, in my job as—I did write that as Editor in Chief of *Environmental Science and Technology*, one of the leading journals in the world in environmental science and engineering, and I wrote it—that is a part of my job actually.

Chairman HARRIS. Sure, and——

Dr. SCHNOOR. So in the——

Chairman HARRIS. I only have 1–1/2 minutes. Do you feel that there is scientific evidence that would permit you to use the word "cause"?

Dr. SCHNOOR. To cause——

Chairman HARRIS. Yeah, that hydraulic fracturing——

Dr. SCHNOOR. In the context of the film——

Mr. HARRIS [continuing]. Caused——

Dr. SCHNOOR [continuing]. That is what I was talking about.

Chairman HARRIS. So you feel that at the time you wrote in 2010 that evidence indicated——

Dr. SCHNOOR. And regulate refers——

Mr. HARRIS [continuing]. Knowing——

Dr. SCHNOOR. If I could just finish answering the question, "Regulate Baby, Regulate" refers to a lack of regulation that is laid out in the editorial on the oil and gas industry, which caused the Macondo oil well spill, 200 million gallons to the Gulf of Mexico, and has caused problems with pits, ponds and lagoons left over from natural gas——

Chairman HARRIS. Sure. Well, as part of our written questions, I am going to ask you to submit the proof of the use of the word "cause" because I looked over the science. I am convinced that the overwhelming evidence is that it didn't cause it.

Does anyone on the panel disagree with Dr. Young's recommendation that data used to justify regulations should be made publicly available without any—I mean, that should be taken for granted. Controversial data, make it publicly available, and there-

fore do you think the EPA should have taken well over two months or just about two months to release the data associated with a highly controversial study that was a draft report where it is the most important place to release preliminary data, that you are asking people to suggest peer reviewers. Does anybody disagree that they should be total data transparency on an issue that important? Does that hand mean you disagree?

Dr. SWACKHAMER. No, it doesn't, Mr. Chairman. I just wanted to add to that.

Chairman HARRIS. Sure.

Dr. SWACKHAMER. I certainly believe that data should be made available for peer review and that all data that goes into making conclusions in a scientific study should be made available, but it is important that the data be through a quality review and that the data has been qualified assured before it is released.

Chairman HARRIS. But it should have done that before you wrote the initial draft report, right?

Dr. SWACKHAMER. Absolutely.

Chairman HARRIS. Thank you. Okay. I am talking about the draft report. Thank you very much.

Mr. Miller, we have—they just called votes but we have plenty of time for the five minutes or so.

Mr. MILLER. Drs. Schnoor, Swackhamer and Mr. Greenbaum, Dr. Young proposed funding data generation and data analysis separately so one group would collect and stage the data and post it and then a separate group of scientists with separate funding would analyze the data. Do you agree with that proposal?

Mr. GREENBAUM. Actually, I would not agree with that, partly because the design, the building of the database is a fundamental scientific enterprise. It is not some rote process by which somebody just goes out and collects data and then makes it available so that I do think that—and we have a data access policy, a very open data access policy since long before the Shelby amendment. We have always assumed that the first data collection is being done. We are funding it. People are designing a study and then collecting the data to do it. Now, having said that, once they have had the chance to go through their data, make their data—analyze it, we have had a chance to peer review that, we very strongly believe they should be able to make that data publicly available and anybody should be able to come in and get it, and that is what I referred to in my testimony. We have actually put data from our studies up on the Web. So I don't think it should be totally separate but I do think there should be access to the underlying data afterwards.

Mr. MILLER. Okay. Succinctly, Dr. Swackhamer.

Dr. SWACKHAMER. I would agree very much with what you just heard. Thank you.

Mr. MILLER. Okay. Dr. Schnoor.

Dr. SCHNOOR. Again, the policy is that if you ask for the data, you will get it from the journals such as ours, but I would say that the general impression is that the person who generated the data should be able to publish and work on it first, so that it is a bit different than what Dr. Young is proposing.

Mr. MILLER. Dr. Young, I would be delighted to, but we just don't have time.

I now yield the balance of my time to Mr. McNerney, my time to Mr. McNerney.

Mr. MCNERNEY. Well, thank you.

I think the peer process is kind of what we are talking about here then. Apparently, from what we are hearing from the panel this morning, most submitters do supply data with papers. Is that your impression? I see some shaking yes and some shaking no.

Dr. SCHNOOR. Actually in our journal, they do, and I think Dr. Young agrees with that, but not every journal maybe has the same policy.

Mr. MCNERNEY. But what is coming out of this is that most reviewers don't ask for the data. So, I mean, are we in a position where we have to say if you want to review this, you are going to have to look at the data? And I don't think that is a viable option because aren't going to want to review papers if you do that.

The other thing that kind of came out earlier was that important papers are reproduced, which is actually a much bigger step than just a peer review. If you can reproduce a paper, you have done a lot more than just reviewing. So requiring important papers to be reproduced, now, that is another level of expense and delay and so on. Where can we go that we don't have to take those kind of steps? Yes, Dr. Young.

Dr. YOUNG. I refer you to a study that was done in the 1950s, type A personality and heart attacks. We all know it is true, don't we? That study was replicated twice and both times it failed. After the first replication, a learned group of scientists got together and said the second study was wrong. Well, when it was tried to be replicated a third time and it was—it didn't replicate, it meant the first study itself was wrong. So a false positive occurred in the first step, two more steps, and it has taken 20 years and that is a legend in our time right now. I will tell you, Congressman, you don't have to lay back, you don't have to be cool. You can be a type A personality and you are not going to get a heart attack.

Mr. MCNERNEY. There aren't any type A personalities in here. Don't worry about it.

Dr. YOUNG. What I am saying is that if you release the data as soon as possible, the scientific process can take over, and we are talking about not just a correct answer but how fast you get it. Type A personality took 20 years to overturn, and it is still a legend, so we want it to be fast and we want——

Mr. MCNERNEY. Let Mr. Greenbaum answer.

Mr. GREENBAUM. Science is a messy business. There are thousands and thousands of papers published every year, and they can have a wide variety of results. They get peer reviewed. I did note that the quality of peer review can vary according to journals. There is a hierarchy, though, and as papers become—first of all, as they get replicated, and I even know of cases where EPA has funded explicit attempts, independent attempts to replicate important results, they and Congress and industry came to us to re-analyze some key studies. As you get closer to key studies that are going to be making a difference in a risk assessment or in a decision on an ambient air quality standard, then you do need to get to the next level of understanding what the underlying data is, what the peer review is. I would agree with you, we cannot have detailed re-

analysis of every single paper out there or we would have paralysis. On the other hand, when we get to the really key studies, I think there is a higher standard, and that is part of why HEI was set up, but we are not the only ones. There are mechanisms for doing that.

Chairman HARRIS. Thank you very much. I thank the witnesses for their valuable testimony and the Members for their questions.

The Members of the Subcommittee may have additional questions for the witnesses, and we will ask you to respond to those in writing. The record will remain open for two weeks for additional comments from Members.

The witnesses are excused with my thanks, and the hearing is adjourned.

[Whereupon, at 11:12 a.m., the Subcommittee was adjourned.]

Appendix I

Answers to Post-Hearing Questions

ANSWERS TO POST-HEARING QUESTIONS

Responses by Mr. Daniel Greenbaum,
President and Chief Executive Officer,
Health Effects Institute

U.S. HOUSE·OFREPRESENTATIVES
COMMITTEE ONSCIENCE, SPACE, AND TECHNOLOGY
Subcommittee on Energy & Environment

Hearing Questions for the Record
The Honorable Andy Harris

Fostering Quality Science at EPA: The Need for Common Sense Reform Day II
February 3, 2012

Mr. Daniel Greenbaum

1. In discussing problems with the EPA Science Advisory Board process, Mr. Walls noted that "qualified scientists from industry should be given equal consideration" to serve on advisory panels. Do you support that recommendation?

   I do, and made that comment in my written testimony, so long as the scientist and his company do not have a direct or readily perceivable financial conflict of interest in the outcome of the particular science review at hand. For example, there are many reviews of chemical risk for which the knowledge and expertise of industry scientists would be extremely valuable, and credentialed industry scientists should be allowed and encouraged to serve. However, in the case of a substance in which the scientist's company has a direct financial interest in the outcome (e.g. a risk assessment of formaldehyde and a scientist that works for a major wood products company that uses formaldehyde based products in its production), the industry scientist should not be allowed. (Note that this is the same standard that is applied by HEI and the National Academy of Sciences, and it would also apply to an academic scientist who holds any significant amount of stock in the same wood products company.)

2. Many EPA science activities are housed within regulatory offices. For example, nearly half of EPA's laboratories do not reside in the Office of Research and Development. In your view, should scientific activities be organizationally insulated from regulatory activities to ensure objectivity and balance?

   It would be difficult to entirely isolate the scientific evaluation and synthesis work conducted within the program offices from the programmatic decision process, because that would likely risk NOT having the best science injected at all stages of the decision making process. However, the research itself can and should be done independent of the programs, and as I and others said at the hearing, it is critical that science evaluation and synthesis conducted anywhere in the Agency be subjected to the same high standards of transparency and peer review. While this does occur in some case now (I noted the process by which the Office of Air and Radiation NAAQS risk and policy assessment documents are intensively and publicly peer reviewed by the Clean Air Scientific Advisory Committee) the quality of such peer review is not uniform across the agency.

3. I understand that HEI focuses primarily on air quality research. In your view, would a cofounded organization structured similar to HEI be able to provide quality assessment and reanalysis information for other environmental issues such as chemical assessments or focused water research?

   There is no fundamental barrier to applying the principles of the HEI model to many other areas requiring scientific research, evaluation, and synthesis of the highest integrity and credibility.

The principle needs for establishing such a model are commitments by both the regulatory agency (EPA) and industry to:

- *support the establishment of a truly independent Board of Directors and Scientific Committees that can implement the scientific activities without undue involvement of the sponsors;*
- *provide funding for the effort over a multi-year period and in a balanced form, so as to take the issue of funding and credibility "off the table;" and*
- *regularly contribute useful information on the most pressing scientific issues and questions that need to be addressed.*

If these conditions can be met, the HEI model could be applied to a wide range of health and other environmental science issues. Having said that, the HEI model may not be necessary for every aspect of the science underlying regulatory decisions (which needs to be continually improved within EPA), but may best be applied to the most controversial areas of scientific debate, where the impacts of potential decisions can be greatest (e.g. air pollution, groundwater contamination from energy activities, certain chemical risk assessments).

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

Hearing Questions for the Record
The Honorable Randy Neugebauer

Fostering Quality Science at EPA: The Need for Common Sense Reform Day II
February 3, 2012

Mr. Daniel Greenbaum

1. What type of research does the EPA currently conduct to confirm predicted health outcomes of previously promulgated rules? In what ways can we improve existing efforts to examine the real effects of EPA rules, and what else can the Agency be doing to increase accountability for health and environmental predictions?

   EPA has engaged in some significant efforts to re-visit whether actions they have taken have had the health benefits that they predicted they would have, most notably the mandated "Section 812" analyses in the Clean Air Act that require them to look back at the costs and benefits of the Act. However, this effort, and most others, have not been based primarily on actual measurement of changes that have occurred, but on modeled estimates of the changes that are likely to have occurred which, although done with significant peer review, cannot actually measure what has happened.

   EPA has, along with HEI's industry sponsors, strongly supported HEI's efforts to conduct "health outcomes" or "accountability" research which attempts to actually measure whether there have been improvements in air quality and health in response to EPA rules and other actions. To further enhance this effort, EPA could (a) build into every major new rule a "health outcomes research plan" which would plan out the collection of air quality and health data from before the rule is implemented to an appropriate period of time after implementation and (b) engage HEI and other organizations in producing this research in an independent fashion so as to ensure it is a fair and open evaluation of the rule's effectiveness.

2. Are there any legitimate concerns about making public the data sets that attempt to justify EPA regulations? Are there real concerns about confidentiality, and if so, do they outweigh the necessity of accountability, transparency, and open and sound scientific examination?

   There are legitimate concerns about ensuring that the personal medical and other data contained in the records of subjects involved in research (e.g. members of a population of people being studied in an epidemiologic study) are never divulged and linked to that individual. However, there are readily available mechanisms for masking all personal detail so that this breach of privacy would never occur, and this should allow academic investigators, government agencies, and private companies to make the data underlying their studies available. (Note that these procedures may result in slightly smaller data sets, as the masking of individual identity is harder if the people come from small communities (e.g. where there may only be one death each day and it would be possible to link that death to a particular individual). But that should not undermine the value of the broader data set.)

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

Hearing Questions for the Record
The Honorable Brad Miller

Fostering Quality Science at EPA: The Need for Common Sense Reform Day II

February 3, 2012

Mr. Daniel Greenbaum

EPA ORD Realignment

1. In the realignment of the Office of Research and Development programs, has the reduction and integration of the number of programs down from 13 to 6, proven to be a more efficient and effective strategy for EPA-ORD research activities? How has this alignment improved ORD's coordination with the program and regional offices? What more can and needs to be done to strengthen the EPA overall research enterprise?

   It is still early in the implementation of this new realignment, but it appears to be a much better and integrated way to plan out, on a multi-year basis, research strategies for a series of highly interrelated topics (e.g. Air Quality, Climate, and Energy all in one plan). It is not yet clear how this will change and/or improve the coordination with the program and regional offices, and both the EPA Science Advisory Board and a separate National Research Council committee on Science for EPA's Future are examining how this can be better integrated agency-wide.

   This issue – of better integrating the ORD science and scientific activities across the agency and the assurance of the same level of scientific transparency and quality in all places - is the single largest challenge and opportunity for ensuring that EPA science is enhanced across the board.

Responses by Dr. Deborah L. Swackhamer,
Professor, Environmental Health Sciences,
University of Minnesota
and Chairwoman, EPA Science Advisory Board

U.S. House of Representatives
Committee on Science, Space, and Technology
Subcommittee on Energy and Environment
Response to Hearing Questions for the Record
"Fostering Quality Science at EPA: Need for Common Sense Reform Day II"

By Deborah L. Swackhamer, Ph.D.
Professor, University of Minnesota
Chair, US EPA Science Advisory Board

Hearing Questions from the Honorable Andy Harris:

1. The Bipartisan Policy Center's 2009 report, "Improving the Use of Science in Regulatory Policy" was mentioned during the hearing. This report made several suggestions that may be useful in guiding this Subcommittee's efforts to reform regulatory science, including:

   • "Studies used in the formulation of regulation should be subject to data access requirements equivalent to those under the Data Access Act."
   • "The process of conducting literature reviews" and "the process of naming advisory committees" should be made more transparent.
   • "Agencies should avoid turning repeatedly to the same scientists for service on advisory committees."
   • Executive branch agencies need to "help clarify for both officials and the general public which aspects of disputes are truly about scientific results and which concern policy."
   • "Policy makers should be wary of conclusions of risk that are expressed as a single number."
   • "Federal agencies need to experiment with ways to increase the number of scientists who participate in peer review."
   • "In presenting the conclusions of literature reviews, agencies and their scientific advisory committees need to be as open and precise as possible in discussing levels of risk and uncertainty."

   Do you agree with any or all of these recommendations? Do you have any additional comments or advice in pursuing these goals?

The Bipartisan Policy Center's 2009 report was directed to the entire Federal Executive branch, and not to EPA specifically. The EPA SAB was not asked to review or advise the report for the EPA Administrator, and so cannot provide comments on the report's recommendations. The Subcommittee is directed to EPA administration for the agency's view on these recommendations.

2. In discussing problems with the EPA Science Advisory Board process, Mr. Walls noted that "qualified scientists from industry should be given equal consideration" to serve on advisory panels. Do you support that recommendation?

In my years on the SAB and as Chair, our Board and Panels have had balance, including membership from qualified scientists from industry. In my experience, their contributions have been immensely valuable.

3. Many EPA science activities are housed within regulatory offices. For example, nearly half of EPA's laboratories do not reside in the Office of Research and Development. In your view, should scientific activities be organizationally insulated from regulatory activities to ensure objectivity and balance?

The organizational structure of EPA is the responsibility of the EPA and the SAB has never been asked to advise on the overall organizational structure of the Agency. Good science and relevant outcomes can be found in ORD as well as in the Program and Regional offices.

Hearing Questions from the Honorable Randy Neugebauer:

1. What type of research does the EPA currently conduct to confirm predicted health outcomes of previously promulgated rules? In what ways can we improve existing efforts to examine the real effects of EPA rules, and what else can the Agency be doing to increase accountability for health and environmental predictions?

The SAB is supportive of evaluating health outcomes as a result of EPA actions. The SAB recommends the need to do such evaluations to "close the loop" and then make appropriate adjustments as needed in its recent draft report on the integration of science and decision-making at EPA[1]. However, the SAB recognizes that conducting such evaluative studies can be very expensive and difficult to conduct.

2. Are there any legitimate concerns about making public the data sets that attempt to justify EPA regulations? Are there real concerns about confidentiality, and if so, do they outweigh the necessity of accountability, transparency, and open and sound scientific examination?

The SAB recommends that literature and data used by EPA be peer-reviewed and made available to the public. When the SAB conducts peer reviews and evaluations, it prefers to review all data associated with the document in question. It is my experience that EPA makes its best effort to provide all data to the SAB, subject to ethical and legal restrictions.

[1] [1] Science Integration for Decision Making at the U.S. Environmental Protection Agency (EPA) (draft January 5, 2012)

Questions from the Honorable Brad Miller:

EPA-SAB

1. Testimony at the hearing alluded to concerns that the SAB and EPA staff is "cozy" in their peer review of EPA activities. To ensure that this is not the case, what processes are in place to prevent conflict of interest or undue influence?

As a FACA committee, the SAB has strict processes that must be followed in its deliberations. All SAB meetings (including phone calls) are announced in the Federal Register and all discussion, presentations, deliberations are completely open to the public (i.e. very transparent). All SAB members are required to submit a conflict of interest form for EPA evaluation for each new advisory activity. We are explicitly instructed not to discuss SAB activities outside of this public venue (i.e. no private deliberations) and we are explicitly instructed not to interact with EPA staff on the activity at hand. All questions for EPA staff outside of the official meeting must go through the Designated Federal Officer (DFO) who has responsibility for the SAB committee or panel. The SAB takes FACA, transparency, and conflict of interest very seriously.

EPA ORD Realignment

2. In the realignment of the Office of Research and Development programs you both described in your testimony, has the reduction and integration of the number of programs down from 13 to 6, proven to be a more efficient and effective strategy for EPA-ORD research activities? How has this alignment improved ORD's coordination with the program and regional offices? What more can and needs to be done to strengthen the EPA overall research enterprise?

The SAB is supportive of the realignment of EPA ORD programs. To date, it appears that the realignment has led to greater interdisciplinary interactions and greater communication. It is too early to tell if it has been proven an effective strategy for research outcomes. This realignment should result in improved coordination with the Program and Regional offices by its very design.

Responses by Mr. Michael Walls,
Vice President, Regulatory and Technical Affairs,
American Chemistry Council

Responses of Michael P. Walls
American Chemistry Council
Hearing Questions for the Record
March 6, 2012

The Honorable Andy Harris

1. **The Bipartisan Policy Center's 2009 report, "Improving the Use of Science in Regulatory Policy" was mentioned during the hearing. This report made several suggests that may be useful in guiding this Subcommittee's efforts to reform regulatory science, including:**

- **"Studies used in the formulation of regulation should be subject to data access requirements equivalent to those under the Data Access Act."**
- **"The process of conducting literature reviews" and "the process of naming advisory committees" should be made more transparent."**
- **"Agencies should avoid turning repeatedly to the same scientists for service on advisory committees."**
- **Executive branch agencies need to "help clarify for both officials and the general public which aspects of disputes are truly about scientific results and which concern policy."**
- **"Policy makers should be wary of conclusions of risk that are expressed as a single number."**
- **"Federal agencies need to experiment with ways to increase the number of scientists who participate in peer review."**
- **"In presenting the conclusions of literature reviews, agencies and their scientific advisory committees need to be as open and precise as possible in discussing levels of risk and uncertainty."**

Do you agree with any or all of these recommendations? Do you have any additional comments or advice in pursuing these goals?

Response:

ACC agrees with the cited recommendations of the Bipartisan Policy Center's (BPC) report. In particular, ACC agrees with the recommendations that focus upon improving objective and comprehensive scientific analysis that is developed and used by agencies and on enhancing the scientific advice provided to federal programs.

In addition to the BPC recommendations, however, there is a critical need for federal agency risk assessment programs to adopt a consistent weight-of-evidence framework. A weight-of-the-evidence approach will help ensure that all relevant and reliable data, including negative results, can be systematically reviewed, given appropriate weight, and integrated in a manner that provides a robust understanding of the mode of action and the potential hazards and risks that environmentally relevant levels of exposure could pose.

Independent scientific peer review plays a critical role of assuring agency science work products are objective, comprehensive and full transparent. Scientific peer review entails a detailed independent evaluation of the scientific work product including the critical analysis of

assumptions, calculations, extrapolations, alternate interpretations, methodology, criteria, and conclusions. Given the pivotal role that peer review plays in agency scientific determinations, there is a need for to agencies to evaluate their scientific peer review programs and adopt improvements. Such improvements should include:

- Providing opportunity for more meaningful public comment on draft assessments to include a facilitated public dialogue session with stakeholders on the key issues and also on the draft peer review charge questions.
- Ensuring peer review panels are composed of experts across the necessary disciplines, with selection based principally on scientific expertise. Affiliation and employment, and funding (either past or present) that are not direct conflicts of interest should not be used to exclude individuals. The procedures to appoint peer reviewers should assure both objectivity and lack of significant bias of the individual reviewers, and a balance of scientific perspectives across the peer review panel. Policies and procedures for full disclosure of conflict of interest and bias, as described in the NAS Conflict of Interest Policy, should be clearly defined and implemented.
- Structuring the peer review process to provide sufficient opportunity for robust discussion and consideration of public comments by the independent scientific peer reviewers. Peer reviewers also must be afforded ample time to devote to peer reviews.
- Responding in writing to comments as part of the assessment revision process that follows the public comment and peer review phases. Where the Agency elects not to address a peer review finding or recommendation, or a significant public comment, EPA shall issue a written justification for such action.
- Conducting a separate and independent review of the assessment after public comment and peer review comments are incorporated, consistent with NAS practices for scientific report review of NAS reports, to ensure that the agency assessment addresses comments received, is supported by the totality of the scientific evidence, and is consistent with established report review criteria.
- Certifying that an agency assessment reflects best available science, that public comments and the findings and recommendations of independent peer review have been addressed, and that the report is impartial and objective.

2. **Last year, EPA's Science Advisory Board accepted comments from stakeholders on ways to improve public participation in the Board's meetings and reviews, and made some changes to their process. Did these changes address all of the Council's concerns?**

Response

In June 2011, the EPA Science Advisory Board (SAB) Staff Office solicited public comment on ways to enhance public involvement in SAB activities. The American Chemistry Council, among other interested stakeholders, provided written and oral suggestions to SAB. We were pleased to see that the Staff Office has developed additional practices to enhance public involvement (see http://yosemite.epa.gov/sab/sabproduct.nsf/WebSABSO/PublicInvolvement?OpenDocument

ACC, however, continues to have concerns with the SAB process.

The SAB Staff Office must ensure that the SAB peer reviewers fully understand their independent roles as peer reviewers. In general, ACC believes that members of EPA's SAB office (including the Designated Federal Officials) perform their review function diligently and appropriately. At times, however, it appears that peer reviewers are overly deferential to EPA programs, and are reluctant to be seen as criticizing EPA program staff. Also, EPA program staff are often given unfettered ability to comment throughout the peer review meetings and their constant presence may have a chilling effect on frank and open discussion among the peer reviewers. In addition, in selecting peer review panel members, the foremost consideration should be given to expertise. Qualified scientists from industry should be given equal consideration for appointment based on the subject matter, and in accordance with applicable conflict of interest provisions. Authoritative bodies agree, including the National Research Council of the National Academies and the Society of Toxicology.

ACC's concerns are particularly applicable to EPA's recent announcement that it has established a dedicated SAB peer review panel for assessments in the Integrated Risk and Information System (IRIS). The National Academy of Sciences (NAS) noted in its recent review of the IRIS formaldehyde assessment several persistent problems with peer review of draft assessments. It is vital that the dedicated panel operate more independently from EPA, and create processes that enhance public and stakeholder confidence in SAB reviews of IRIS assessments.

ACC is concerned that a standing panel, which uses the same reviewers for multiple assessments, may not be sufficiently independent from the Agency. The OMB Information Quality Bulletin for Peer Review (see http://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2005/m05-03.pdf) , states that for highly influential scientific assessments (such as the typical IRIS assessment):

> Agencies shall avoid repeated use of the same reviewer on multiple assessments unless his or her participation is essential and cannot be obtained elsewhere." For influential scientific assessments, "Agencies are encouraged to rotate membership on standing panels across the pool of qualified reviewers.

Similarly, the EPA Peer Review Handbook (see: http://www.epa.gov/peerreview/pdfs/peer_review_handbook_2006.pdf), states that

> There is no prohibition on using the same peer reviewer more than once on the same produet or for multiple products of the same office. However, it is preferable to use different people each time to provide a broader perspective. When using a contractor to provide peer review services, you should recognize that contractors may have a "pool" of reviewers that they use regularly. If the same peer reviewers are used repeatedly, they may lose their independence (or the appearance of independenee) from the work product(s). If a peer reviewer is asked to participate in multiple reviews of the same product it should be noted in the peer review record.

Later in the EPA handbook, the Ageney states:

> Although persons who are familiar with and have a substantial reputation in the field are often called upon repeatedly to be reviewers, it is important to keep a balance with new

people who bring fresh perspectives to the review of a work product. The idea here is to avoid the repeated use of the same reviewer on multiple assessments unless his/her participation is essential and cannot be obtained elsewhere.

We recommend that EPA follow the OMB suggestion that "the agency rotate membership among qualified scientists in order to obtain fresh perspectives and reinforce the reality and perception of independence from the agency."

3. **Generally speaking, do you think your members would be comfortable with an EPA policy to make the underlying data and models used in regulatory decisions publicly available?**

Response

In general, ACC and its members would support an EPA policy to make the underlying data and models used in regulatory decision making publicly available. Clearly, objective evaluation of data is a foundation of science-based regulatory decision-making. The public release of data, methods, and models used in a scientific analysis in a form that allows independent peer reviewers, and stakeholders, to independently verify the Agency's calculations (and conclusions) and to reanalyze the data using other statistical methods and alternative models will improve transparency and increase public and stakeholder confidence in the decisions being supported by the agency's scientific analyses.

In many instances it is important to evaluate plausible alternative modes of action, models and assumptions, the choices made among those alternatives, and impacts of one choice vs. another on the assessment. Without the data, the impact of key assumptions and extrapolations used by the Agency in the analysis cannot be readily discerned.

In ACC's view, it is also important to distinguish between "complete data sets" and "sufficient data sets." For example, one legitimate concern with making "all" health and safety data "public" is data compensation. Companies develop health and safety data of this nature at considerable expense. If complete data sets were always made public, the "public" at large and competitors could make use of it in regulatory programs -- both inside and outside of the U.S. It is important that those who developed the data should be compensated for the time and expense of developing the data.

Data compensation is a well-recognized issue and has been addressed through some EPA regulations (e.g. under the Federal Fungicide, Insecticide and Rodenticide Act (FIFRA) dealing with pesticides) and general industry practices for sharing and being compensated for data.

A second potential practical concern of making data sets publicly available is the potential for a burdensome "data dump" on the Agency. A solution to this problem was developed by EPA in consultation with industry for the U.S. High Production Volume (HPV) Chemical Challenge Program, which began in 1998. In the HPV Program hazard data and other relevant scientific information for U.S. HPV chemicals (either existing or newly acquired information) were submitted to EPA.

From a practical standpoint, EPA determined that it was not reasonable to attempt to create an electronic version of full study reports (especially old reports from the 1960s or earlier) for the HPV Challenge program. See: http://www.epa.gov/hpv/pubs/general/robsumgd.htm . Instead, detailed electronic summaries of full study reports were prepared that contained the appropriate technical information for that particular endpoint. The term "robust summary" was used to describe this technical content.

Robust study summaries are intended to provide sufficient data/information to allow a technically qualified person to make an independent assessment of a given study report without having to go back to the full study report. They were also intended to allow EPA to reach decisions whether the existing data, together with other relevant information, were sufficient or whether additional testing would be needed. The details of these robust summaries -- "sufficient data sets" -- also enabled the public, including environmental NGOs and animal welfare stakeholders, to evaluate proposed test plans in the HPV Challenge program.

A robust study summary therefore might be a path forward to ensure "sufficient data sets" are made public, since a robust summary reflects the objectives, methods, results, and conclusions of the full study report. So, while there may be practical concerns about overly burdening the Agency with a "data dump" of "complete" data sets, (which the Agency doesn't always need to make its decisions), the robust study summary approach is a viable solution to this potential concern.

A third potential concern relates to requirements to submit data and information before scientists have had a chance to analyze it and publish the data themselves. One of the witnesses at the Feb. 3 hearing called for the scientists who developed data for the government to turn the data sets over immediately to other scientists who would analyze the data. This proposal was recommended as a means of avoiding problems of bias, inadequate data analysis and similar concerns by the scientists who collected the data.

A requirement to submit all data immediately would remove an important incentive for scientists to conduct research and collect data. The scientific community relies on scientists to develop new hypotheses, design new methods and innovative approaches to study these hypotheses, and to collect, analyze and publish their research results in the scientific literature. These researchers should be afforded the opportunity to analyze and publish the results of their research efforts before others are given the opportunity to analyze the data In sum, timing of the release of scientific data is certainly one concern with making "all" data sets which EPA might rely upon, publicly available.

The Bipartisan Policy Center report mentioned in your first question ("Improving the Use of Science in Regulatory Policy," available at http://www.bipartisanpolicy.org/sites/default/files/BPC%20Science%20Report%20fnl.pdf recommends that "studies used in the formulation of regulation should be subject to data access requirements equivalent to those under the Data Access Act (Shelby Amendment) and its implementing Circular regardless of who conducted or sponsored the study. In addition, the Data Quality Act and Agency implementing guidelines provide benchmarks and criteria that are to be followed by agencies in disseminating data and other relevant information that support regulatory evaluations.

4. **A recent joint report from the EPA's Science Advisory Board and Board of Scientific Counselors recommended that the Agency "include sustainability in its research vision" in order to allow "EPA to adopt sustainability as a core principle to inform decisions and actions." Is this emphasis on sustainability appropriate for EPA's research and science activities? Do you have any concerns about this new mission?**

Sustainability is primarily concerned with maximizing benefit, while addressing risks of concern, rather than being an exercise focused mainly on achieving risk based standards. ACC believes that adopting sustainability as a core principle to inform decisions and actions will in fact enable EPA to formally incorporate consideration of benefits in the their risk-benefit evaluations – but only if it is implemented appropriately. A sustainability framework will encourage EPA to take on a more integrated and systems-based approach to environmental management that can be superior to the current patchwork approach. A recent report by the National Academy of Sciences ("Sustainability and the U.S. EPA," (2011)) outlined one possible approach to implementing sustainability in EPA activities.

The ACC believes that the private sector, and our industry, in particular, has a rich experience in incorporating sustainability into our business processes. We believe the Agency would benefit significantly from engaging stakeholders in developing a strategy to operationalize sustainability in its vision.

5. **Many EPA science activities are housed within regulatory offices. For example, nearly half of EPA's laboratories do not reside in the Office of Research and Development. In your view, should scientific activities be organizationally insulated from regulatory activities to ensure objectivity and balauce?**

Response

As one of the Nation's most regulated industries, ACC member companies expect high quality science – and reliable assessment processes – to underpin effective and efficient regulatory decisions by the Federal government. It is critically important that EPA laboratories conduct research that is mission-critical and can be held to the highest standards of excellence.

Part of ensuring this quality requires that EPA make certain that research is conducted in an objective manner that is not influenced by a desire for a predetermined outcome. If we look at the IRIS program, there is a lack of a consistent, coherent, science-based framework that binds the agency to an appropriate and transparent approach for weighing evidence, considering uncertainty, and keeping up with advances in the field. These deficits greatly impact stakeholder confidence in IRIS database.

Objectivity and high quality are not necessarily a function of where an assessment program is located or organized. The IRIS program is housed in an Office of Research and Development Laboratory (the National Center for Environmental Assessment) and yet we see that the independence from regulatory activities has not necessarily guaranteed the objectivity and high quality science that all stakeholders would like to see.

A draft report released by the EPA Science Advisory Board (SAB) in January 2012, noted that scientific integration could be strengthened and that the agency's focus on program and disciplinary "silos" remains a significant barrier to science integration. ACC supports measures to improve scientific integration that result in further enhancements in science based regulatory decisions.

The Honorable Randy Neugebauer

1. **What type of research does the EPA currently conduct to confirm predicted health outcomes to previously promulgated rules? In what ways can we improve existing efforts to examine the real effects of EPA rules, and what else can the Agency be doing to increase accountability for health and environmental predictions?**

Response

ACC is not aware of any standardized approaches or practices used by EPA to confirm predicted health outcomes to previously promulgated rules. While EPA does have access to anecdotal information (for example, we know that blood lead levels in Americans decreased substantially after lead was removed from most gasoline), a more systematic approach to collecting and evaluating this information would be welcomed.

2. **Are there any legitimate concerns about making public the data sets that attempt to justify EPA regulations? Are there real concerns about confidentiality, and if so, do they outweigh the necessity of accountability, transparency, and open and sound scientific examination?**

Response

ACC's response to Dr. Harris' third question outlines a number of general concerns that may arise from requirements to make public data sets that justify EPA regulation.

One potential disconnect in considering the release of data sets that justify federal regulation is that many federally supported researchers may have no idea that the work they are doing may someday be the basis, or part of the basis, of a regulatory action by some agency before which they have never appeared and about which they know little. It would be natural to assume that there would be some resistance in the research community at a broad requirement for disclosure of data sets generated by researchers without prior knowledge of the possible use as a basis for regulation, and without an opportunity to full leverage the scientific and research potential of that data.

In ACC's view, it may be difficult to implement a blanket requirement to disclose the data sets underlying regulatory programs. One approach would be to provide incentives for enhanced data sharing. That might include resources for investigators to clean up data sets, meet data quality criteria, and submit them to a managed database.

Finally, there are indeed important and legitimate concerns regarding the protection of confidentiality with respect to some data sets generated by private research. For example, much of the innovation in chemistry depends on confidential chemical identities, which often cannot be patented. ACC strongly supports transparency and the public availability of health and safety information about potential effects of chemicals, while still protecting competitive business interests. We believe these often competing interests can be reconciled by distinguishing between the full disclosure of health and safety effects information and the nondisclosure of legitimate confidential business information and confidential chemical identities.

Responses by Dr. Richard Belzer,
President, Regulatory Checkbook

REGULATORY CHECKBOOK

Richard B. Belzer, Ph.D.

Committee on Science, Space, and Technology
Hearing entitled
"Quality Science at EPA:
Perspectives on Common Sense Reform- Day II"
February 3, 2012

Responses to Questions for the Record
Requested February 21, 2012

Revised March 6, 2012

QUESTIONS FROM CHAIRMAN ANDY HARRIS

1. ***The Bipartisan Policy Center's 2009 report, "Improving the Use of Science in Regulatory Policy" was mentioned during the hearing. This report made several suggestions that may be useful in guiding this Subcommittee's efforts to reform regulatory science. Do you agree with any or all of these recommendations? Do you have any additional comments or advice in pursuing these goals?***

As a preface to my reply, I wish to make three observations that span the range of the BPC committee report's conclusions and recommendations. First, there should be no question that the committee approached its assignment with seriousness, public spiritedness, and the best of intentions. It is therefore inappropriate to judge its insights and commendations based on any factor other than merit.

Second, the BPC committee's task was enriched by the participation of individuals who had served, at one time or another, on both the analytic and decision making sides. This experience makes a fine illustration of Graham Allison's Model 3 of bureaucratic politics: "Where you stand depends on where you sit."[1]

Third, the good faith and rich experience of the members of the BPC committee do not automatically translate into practical or effective solutions.

[1] Allison (1971).

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Some of the committee's recommendations are basically fond wishes for someone—anyone—to implement by magic wand. Other recommendations appear to be plausible ideas that unfortunately are grounded on dubious premises.

The BPC committee's recommendations should be subjected to a sequential three-part analysis:

1. If the recommendation could be implemented immediately at no cost, would it solve the identified problem? If it wouldn't, then it is unclear why Congress should devote much time to it.
2. If the recommendation could solve the identified problem, is there a practical strategy proposed by which to implement it? If the recommendation cannot be implemented, then its interest will be limited to academics and theoreticians.
3. If there is a practical strategy by which the recommendation could be implemented, what unintended consequences could occur; which of them are likely; and how could they be prevented?

With that preface, my responses to each of the bulleted inquires follows below.

- ***"Studies used in the formulation of regulation should be subject to data access requirements equivalent to those under the Data Access Act."***

I am generally in agreement with the objective of the BPC committee recommendation, but it appears to be too timid. Data access rules "equivalent to those" under the Data Access Act cannot solve the problem the BPC committee identified. Agencies can and do behave strategically to evade the Shelby Amendment. They often rely substantially on the work of federally-funded researchers but intentionally do not obtain their data. Meanwhile, OMB Circular A-130 is burdensome and ineffective. In short, this recommendation fails the first element of my three-part test.

A SUPERIOR ALTERNATIVE

In my testimony before the Committee, I said the full disclosure of data, models, and assumptions should be required for scientific information that EPA (or any other agency) either disseminates in a manner connoting agreement or which it relies on, in whole or in part, for regulatory decision making. As I testified:

> Congress could relieve Federal agencies of this conundrum by requiring them to obtain research data if they want to use a Federally funded study as the basis for risk assessment. Requiring disclosure

> imposes only trivial costs on the agencies and does not violate the contractual terms of any Federally-funded researcher. No burden would be imposed on anyone if the agency did not want to use a Federally-funded study as the basis for risk assessment, and no researcher would be compelled to accept Federal research funds to conduct a study likely to be useful in risk assessment.[2]

In my testimony I also agreed with the BPC committee that no distinction should be made based on the source of research funding:

> If an agency wants to rely on a study that was funded by another party, whether that be a state, business, trade association, or nongovernmental organization, nothing currently prevents the agency from asking that this information be supplied, nor is there any general legal barrier to the other party providing it. States, businesses, trade associations, and nongovernmental organizations that want their research to be used for public policy should happily volunteer to provide it.[3]

Even if it were true that industry-funded studies always pointed to lower risk and government/nonprofit studies always pointed to higher risk, that would not justify applying different disclosure standards. Rather, it reinforces the need for the same standards to apply to all scientific information, regardless of the source of funding or the direction in which the research might alter risk assessment.

- ***"The process of conducting literature reviews" and "the process of naming advisory committees" should be made more transparent.***

These excerpts comes from different recommendations addressing different issues, though with an overlapping remedy.[4]

LITERATURE REVIEW

The BPC committee correctly recognized that if the scientific record is not assembled well at the outset, the rest of the process will go badly, and transparency has been lacking with regard to this process. Further, the committee also noted that EPA's criteria for evaluating the literature lacked consistent principles, which is a discreet way of saying that Agency procedures are ad hoc, and in many cases post hoc.

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[2] Belzer (2012), p. 23.

[3] Ibid.

[4] Bipartisan Policy Center (2009), p. 41 [Recommendation Three] and p. 18 [Recommendation Two].

What the committee did not say, but almost surely knew, is that EPA's opacity with respect to conducting literature reviews is intentional. Opacity maximizes the Agency's policy discretion to interpret scientific information as it sees fit. Thus, the committee's recommendation is very nearly a request that EPA bind itself to interpret and use science in predictable ways. Unless it is required by law, this is something neither EPA nor its advisory committees are likely to do. Thus, it fails the second element of my three-part test.

SELECTION OF MEMBERS OF ADVISORY COMMITTEES

The BPC committee's recommendation for transparency in the selection of scientific advisors is similarly at odds with the incentives of EPA officials, staff, and its scientific advisors. Each has incentives that are incompatible with each other, and with good government. Officials and staff alike tend to prefer scientific advisors who agree with them and be loyal defenders of their parochial interests. Officials and staff sometimes agree with each other, but sometimes do not. Thus, conflict is built into the process when an agency allows third parties inside.

It is useful to remember that advisory committees were the last generation's good-government solution to the problem of agencies failing to rely on the best available science. The BPC committee's conclusion that the advisory committee process needed reform indicates that this reform has not been successful and it has had significant unintended consequences. Among those unintended consequences is a new source of pressure to scientize policy.

Being a scientific advisor to EPA confers prestige and power, and for academics it also provides a potential trail to money in the form of research grants. Prestige is obvious; power arises because of the ability to influence policy; and research grants are the mother's milk of academia. It would be naïve to think that scientific advisors are motivated solely by altruism.

The BPC committee called for the process of naming advisory committee members being made more transparent, but it is not clear which problem the committee was trying to solve. The committee said there was a "proper" way advisory committees should be used; implied that agencies' actual use of them was not "proper"; and concluded that transparency in the selection of members would restore "propriety."[5] The committee did not explain how this would happen.

[5] Ibid. p. 68.

Transparency is certainly a good thing, but it isn't likely to be a solution to the underlying problem (i.e., failure to use the best available science) or advisory committees' unintended consequences (e.g., scientization). These unintended consequences can be reduced, but not eliminated, by strictly limiting the role of scientific advisory committee to science. For both scientific and policy advisory committees, there would be additional benefit in making committee selections randomly from lists of qualified individuals, thus reducing the potential for lobbying, logrolling, or various forms of corruption. Ironically, this would make the selection process less transparent, not more so.

RELATED ISSUES

I wish to comment upon one of the committee's recommendations in this area that I find troubling:

> **In general, papers in high impact, peer reviewed journals should be given great weight, and papers that have not been peer reviewed should be treated with skepticism.** However, the quality of peer review varies widely, and journal rankings and impact factors do not guarantee that peer review of a specific paper was performed adequately. **Agencies and scientific advisory committees need to extend their inquiry beyond simply ascertaining whether a paper was peer reviewed; peer review is a necessary but not sufficient determinant of quality.** That further inquiry might explore how the peer review was conducted, how the paper fits into the larger body of literature under review, and perhaps most important, the methodology behind the conclusions described in the paper (for example, how a cohort to study was chosen in an epidemiological study).[6]

This advice is internally inconsistent. The committee says that studies published in "high impact, peer reviewed journals" deserve "great weight," but then cautions that the "quality of peer review varies widely," which of course also is true for "high impact, peer reviewed journals." If that is so, then what could possibly be the justification for giving deference to these studies? It is a short step from giving deference to studies published in prestigious journals to giving deference to studies authored by prestigious researchers. Prestige is not a predictor of accuracy, and what we ought to be seeking to encourage is a scientific culture in which accuracy is what leads to prestige.

[6] Ibid. pp. 41-42; bold in original.

The additional criteria suggested by the committee are early steps of the pre-dissemination review required by OMB (and EPA) information quality guidelines. However, the BPC committee curiously excluded federal information quality standards from the scope of its work—an obvious lost opportunity.[7]

In my testimony, I recommended that Congress require that EPA risk assessments, components, and studies used as the basis for a risk assessment or component, adhere to information quality standards.[8] This is a much better path forward. It would establish a well-defined and consistent performance standard for all scientific information used in support of regulation. It focuses on the objectivity of scientific research and its utility for decision making, not weak, poorly correlated proxies such as the perceived prestige of the journal (or the researcher).

For this reason it is curious that OMB's peer review guidelines do not require adherence to federal information quality standards, even though information quality was advertised as their *raison d'être.* Information quality review also is missing from EPA's Peer Review Handbook.[9] Apparently EPA does not want its scientific peer reviews to get distracted by the burden of ensuring that information quality principles, including objectivity, are met.

- ***"Agencies should avoid turning repeatedly to the same scientists for service on advisory committees."***

This advice from the BPC committee is part of a series of elements in its second recommendation, the purpose of which is as unclear as the theme linking the elements is elusive.[10] Though the committee apparently found it easy to recommend against going to the same well too often, it did not make clear what might be wrong with its water.

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[7] Ibid. p. 43; footnote 6. This is peculiar. No less than nine references in the Report's bibliography concern federal information quality standards. Even more curiously, this footnote does not appear to be relevant to the text to which it is assigned.

[8] Belzer (2012), pp. 24-25.

[9] U.S. Environmental Protection Agency (2006), p. 17. Nothing in the Peer Review Handbook explains how to actually perform an information quality review.

[10] Bipartisan Policy Center (2009). The BPC committee's second recommendation is that the Administration promulgate guidelines implementing the committee's list of recommendations about when to consult advisory committees, how to appoint them, and how they should operate.

There are several problems that can arise if EPA relies repeatedly on the same scientists for advice. The agency may prefer to retain scientists who share the same perspective on the agency's mission and policy direction, or who are more easily managed by the career staff. These scientists would reflect too narrow a perspective, and easily could become so powerful that they are (or perceive themselves to be) de facto regulatory decision makers. As I noted in my testimony, in 2008 the Clean Air Scientific Advisory Committee (CASAC) seems to have succumbed to this misunderstanding of its role with respect to its review of the ozone NAAQS.[11] More recently, in its now-abandoned proposal to "reconsider" the 2008 ozone NAAQS, EPA Administrator Jackson appears to have welcomed the opportunity to implicitly delegate to CASAC the authority to set the standard.[12] The scientization of policy is inappropriate whether it is committed by scientists on an advisory committee or the Administrator herself.

At the same time, there may be good reasons for asking the same scientists to serve over an extended period. For example, a regulatory development process (e.g., the NAAQS) that takes five years may need multiple reviews. If the reviewers change midstream, there is a significant chance that the second group of reviewers will give advice that is contrary to that of the first. While the first group's advice might have been wrong, it's just as plausible that it was right and it is the second group's advice that isn't. The quality of EPA's science is not necessarily enhanced when it receives conflicting advice from multiple committees.

In my view, when EPA gets conflicting advice, it is likely that the reason is not because of the length of service of certain peer reviewers and advisory committee members. Rather, conflicting advice arises because the nature of their role is conflicted. This happens when scientist/reviewers are asked to conduct both a scientific review (which should be neutral and objective) and opine on policy (which cannot be). Whether there is churn among per reviewers and advisory group members may not matter a great deal if they limit their work to science. But it could matter a lot if they are providing policy advice, something the BPC committee explicitly advised against. Thus, the more important first step is to strictly limit scientific reviews to science and get advisory committees out of the business of doing both scientific review and giving policy advice.

[11] Belzer (2012), pp. 19-20.

[12] U.S. Environmental Protection Agency (2009), U.S. Environmental Protection Agency (2010a), p. 2943.

- ***Executive branch agencies need to "help clarify for both officials and the general public which aspects of disputes are truly about scientific results and which concern policy."***

The BPC committee's suggestions in this section of their Report are all interesting and potentially very useful, but they beg the question: why haven't any of them already been implemented? After all, like other regulatory agencies EPA has been subject to centralized review by OMB's Office of Information and Regulatory Affairs for consistency with various regulatory principles for over 30 years.

One answer is that abstract presidential directives and guidelines are not always consistent with the president's agenda or enjoy bipartisan congressional support. Even when these barriers do not exist, they are far from self-implementing. The OIRA professional staff is too small and its authority too limited to be as effective as its advocates hope and its detractors fear.

Even when the stars are properly aligned, OIRA's review process is not structured in a manner that enhances effectiveness. One obvious example: OIRA review occurs too late in the process to ensure that presidential guidelines have been met. Thus, even if guidelines that the BPC committee considered ideal could be drafted, neither OIRA nor anyone else could enforce them. What the BPC committee did not say, but which has to be true, is that the reforms it wants the President to implement are contrary to the bureaucratic interests of the agencies he superintends. Note also that the BPC committee did not propose that OIRA's authorities be expanded enough to enforce them, or that a new organization be established and given this authority.

There are many strategies that might be considered for ensuring that EPA (and other agencies) "clarify for both officials and the general public which aspects of disputes are truly about scientific results and which concern policy." In my testimony, I recommended that Congress require agencies to comply with Federal information quality guidelines and explicitly give the courts the limited authority to adjudicate adherence to these procedures and standards.[13] This recommendation is much more practical and easier to implement than yet another unenforceable presidential guidance document.

[13] Belzer (2012), pp. 21-25.

It satisfies at least the first two elements of the three-part test I presented at the outset.[14]

- ***"Policy makers should be wary of conclusions of risk that are expressed as a single number."***

The BPC committee's advice here is welcome but, if anything, seriously understated and naïve. The notion that risk can be reduced to a single number is a longstanding and durable myth, but unfortunately it is one that Congress encourages.[15] Risk assessment is scientifically uncertain and risk is inherently variable across any population, but policy makers across both the Executive and Legislative branches persist in seeking single number (and single word) characterizations of risk. The use of single numbers (and single words) to represent or describe risk is a common way that policy issues are scientized—i.e., where science is used to make it appear as if no genuine policy issue exists.

The proper way to report risk estimates is by first objectively characterizing the entire distribution, to the extent that is feasible, and then by conducting a rigorous analysis of the most important scientific uncertainties. Not only is distributional variability rarely reported and uncertainty analysis rarely performed, human health risk is not estimated objectively. If adherence to Federal information quality guidelines and standards were statutorily required in an enforceable manner, these longstanding problems would have a short shelf life.

- ***"Federal agencies need to experiment with ways to increase the number of scientists who participate in peer review."***

The BPC committee's concerns about the effectiveness of governmental peer review are certainly well-founded, but I am not persuaded by the committee's diagnosis, which depends on several dubious premises and factual claims that are not well supported by empirical

[14] The most likely unintended consequence would be judicial interference with science. My recommendation does not include giving the courts the authority to review and substantively opine on science, but the courts might not heed such a restriction.

[15] A non-EPA example of some interest: Congress directed the Department of Health and Human Services (through the National Toxicology Program) to determine whether substances are "known" or "reasonably anticipated to be" human carcinogens—special forms of the "single number" problem. However, neither of these conditions is discernable scientifically, and as a result the NTP's biennial Report on Carcinogens has little scientific merit. See Belzer (2012), pp. 19-20.

evidence. For example, it is not clear that peer review has ever been, as the BPC committee claims, "the primary guarantor of integrity in the scientific system."[16]

Scientific integrity has never been guaranteed by anything, and peer review would be a poor insurance policy. This is not because "[s]cientists may feel too burdened to review their colleagues' papers or may do so with insufficient care," or because "[p]eer review is no longer assumed to be a professional obligation," though both concerns may be valid. The reason is more mundane: the historic purpose of peer review has been to allocate limited research funds across competing proposals and to decide which manuscripts among competing submissions deserve to be published in scholarly journals whose pages are limited. Scholarly integrity is a product of training reinforced by character; it is not part of peer review. A more plausible reason for the decline in the quality of peer review, if indeed that has happened, is that academic institutions no longer spend as much time inculcating integrity among junior scholars and valuing character.

There is an increasing tendency for academic scholarship to be infused with policy advocacy. Whereas a generation ago, men and women chose scholarly pursuits to advance knowledge, it seems that an increasing proportion of them do so nowadays to advance hobby horse public policy objectives. This is a trend that so many academic institutions and professional societies foster that it is getting harder every day to find scientists to conduct peer review who are as interested in the science as they are in whether the science advances the achievement of their public policy preferences. For this reason alone, the BPC committee's suggestion that universities and professional societies do a better job fostering peer review seems unlikely to be effective. It fails at least the second element of my three-part test.

A larger problem is that governmental peer review is structured very differently from scholarly peer review and has a completely different objective. Whereas scholarly peer reviewers are never selected by the authors of the manuscripts they review, governmental peer reviewers often are. Whereas scholarly peer reviewers have substantial influence over whether manuscripts are published, governmental peer reviewers never do. Whereas scholarly peer reviewers are supposed to determine whether a

[16] Bipartisan Policy Center (2009), p. 45 (and pullout text on p. 46).

manuscript deserves to be published, governmental peer reviewers are asked to determine whether a risk assessment is correct.[17]

As a result of testimony given by several of the witnesses at the February 3 hearing, the Committee is now aware, perhaps for the first time, that peer reviewers in both scholarly and governmental settings virtually never review a study's underlying data. The Committee also appears to have become aware for the first time that peer review is a poor tool for ascertaining whether the conclusions of research are scientifically correct.

This misunderstanding preceded, but seems to have been exacerbated by, OMB's government-wide peer review guidelines.[18] The stated purpose of these guidelines was to provide a mechanism for pre-dissemination information quality review. Inexplicably, however, OMB's guidelines contained no requirement that peer review actually include pre-dissemination information quality review. Instead of providing a tool for preventing the dissemination of error, the guidelines made it possible for Federal agencies to use peer review to shield themselves from charges that information they disseminated is false.

For these reasons, and others, I am skeptical of the BPC committee's recommendations for improving peer review. Some of them are unlikely to help, even if they could be implemented at no cost, because they are too ambiguous (e.g., "strengthen peer review," "experiment with different ways of conducting peer reviews") or contrary to self-interest (e.g., "[u]niversities should do more to make service as a peer reviewer an expected and appreciated aspect of a scientist's career"). For other recommendations (e.g., "[s]cientific journals should improve the quality control of peer review," or have "clear, publicly accessible conflict-of-interest policies"), the BPC committee neglected to offer strategies for actually implementing them.

In my written testimony, I noted that much of the problem with governmental peer review is that the task relies on scientists but often involves substantial policy content. This policy content could be explicit (e.g., an agency seeks policy advice) or implicit (e.g., an agency seeks ratification of a risk assessment in which the agency's preferred policy is embedded in the methodology). I recommended that scientific peer reviews be strictly limited to science, noting several desirable attributes that would result.[19] In my experience organizing strictly scientific peer review, it has been a

[17] Belzer (2002).

[18] Office of Management and Budget (2005).

[19] Belzer (2012), pp. 21-25.

challenge to persuade scientists that policy matters are truly beyond the scope of the charge, but once they are convinced of this they find the peer review task much more interesting and intellectually stimulating.

One of the challenges of implementing strictly scientific peer review is it requires a fundamental cultural change. This is generally not in the interests of Federal agencies that sponsor a peer review program they consider effective, so it will not occur systematically without congressional action.

- ***"In presenting the conclusions of literature reviews, agencies and their scientific advisory committees need to be as open and precise as possible in discussing levels of risk and uncertainty."***

This is part and parcel of the tyranny of single number risk characterizations, discussed above. What the BPC committee did not acknowledge, but what everyone knows, is that it often is contrary to an agency's actual or perceived interest to acknowledge uncertainty, much less give full attention to it. Agency risk assessors may do the right thing and try to provide full disclosure and analysis of uncertainty, but agency officials often do not want this information. They may find the information too complex or just psychologically unsettling. Further, agency attorneys tend to dislike disclosure of uncertainty because they fear that doing so compromises the defense of promulgated regulations. Courts are obliged by *Chevron v. NRDC* (467 U.S. 837, 1984) to give substantial deference to agency expertise, and deference is easier to give if the agency's experts say they are sure about something even when they have hardly any idea at all.

Like a few other BPC committee recommendations, this one is mostly wishful thinking. Yes, it would be much better if agencies and their scientific advisory committees properly characterized variability and uncertainty when discussing risk. No, this is not going to happen unless and until Congress acts—to remove the ambiguity that creates agency discretion, to replace the Supreme Court's *Chevron* jurisprudence with something else, or to make the full disclosure or variability and uncertainty a nondiscretionary agency duty. To the extent that full disclosure is at least implicitly required by the Federal information quality standard of presentational objectivity, a simple remedy Congress can implement is to mandate that agencies adhere to this standard and make agency compliance judicially reviewable.

2. This Subcommittee's oversight has highlighted a pattern in EPA science: the Agency has protocols or guidelines to encourage transparency, objectivity, or information quality, but these standards are often ignored. What steps could be taken by Congress to ensure these standards are followed?

There are two general problems with the way agencies use guidance. First, they often publish it with the intent of achieving regulatory outcomes without bearing the burden of adhering to the rulemaking requirements of the Administrative Procedure Act. This practice is contrary to law but nonetheless widespread because of the savings to the agency if successful and the expense required to mount a legal challenge.[20] Second, when agencies use guidance properly, such as to limit their own exercise of discretion in order to reduce uncertainty, they often refuse to honor these commitments.

EPA's information quality guidelines provide an excellent example of the latter phenomenon.[21] These guidelines are generally well thought out, but EPA has not been forthright in honoring the commitments they contain. Similarly, EPA's Peer Review Handbook mentions information quality but includes no provisions for actually integrating it into the peer review process.[22]

Several years ago, OMB issued government-wide guidance on the use of guidance.[23] In addition to a number of housekeeping provisions, OMB established a pair of very simple and straightforward substantive principles:

- Guidance must "[n]ot include mandatory language such as 'shall,' 'must,' 'required' or 'requirement,' unless the agency is using these words to describe a statutory or regulatory requirement, or the language is addressed to agency staff and will not foreclose agency consideration of positions advanced by affected private parties" (§ II(2)(h)); and
- "Agency employees should not depart from significant guidance documents without appropriate justification and supervisory concurrence" (§ II(1)(b)).

[20] Congress could ameliorate this discrepancy by allowing plaintiffs who successfully challenge illegal guidance to recover their costs, perhaps including a penalty, from the agency's budget rather than the judgment fund.

[21] U.S. Environmental Protection Agency (2002).

[22] U.S. Environmental Protection Agency (2006).

[23] Office of Management and Budget (2007).

The first principle deals with the problem of using guidance illicitly for regulatory purposes. The second would require senior officials to explicitly waive limits on agency discretion contained in guidance and provide a justification for such waivers. In combination, these two principles reject the misuse of guidance for regulatory purposes and the failure to honor agency commitments.

To make sure that EPA (or any other agency) complies with these principles, Congress would have to codify them in statute.[24]

3. EPA's recently-released final Scientific Integrity Policy "[e]stablishes the expectation that when communicating scientific findings, Agency employees include a clear explication of underlying assumptions, accurate contextualization of uncertainties, and a description of the probabilities associated with both optimistic and pessimistic projections, if applicable." In your view, has the Agency adequately followed this policy in the past?

It is too soon for anyone to give an informed opinion concerning the extent to which EPA has followed this new policy, which has its genesis in a March 2009 Executive Order.[25] My concern with the policy is I have mixed feelings about whether adherence to it is always beneficial. I have no qualms with the excerpt cited above, or with numerous other excerpts and provisions, especially those which promote greater transparency and objectivity. However, these excerpts are accompanied by other text that is problematic at best.

A comprehensive scientific integrity policy must include provisions addressing both the politicization of science and the scientization of policy. After an extended delay, the Office of Science and Technology (OSTP) finally issued government-wide guidance in December 2010.[26] As my written testimony explained, this guidance handles the politicization of science ambiguously and the scientization of policy not at all.[27]

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[24] Agencies try to comply with this second principle without ever tying their hands by including a standard disclaimer, such as the one included in EPA's 2010 Scientific Integrity Policy. See U.S. Environmental Protection Agency (2010b).

[25] Obama (2009b).

[26] Holdren (2010).

[27] Belzer (2012), pp. 2-3.

In some respects, EPA's scientific integrity policy is somewhat better than the OSTP guidance. For example, whereas OSTP prohibits only public affairs staff from altering scientific information, EPA's policy "[p]rohibits all EPA employees, including scientists, managers, and other Agency leadership, from suppressing, altering, or otherwise impeding the timely release of scientific findings or conclusions."[28]

While EPA says its policy "builds upon existing Agency and government-wide policies and guidance documents,"[29] its record of compliance with these other policies and guidance documents does not set an encouraging example. This concern is intensified by the disconnect between EPA's establishment of a cadre of "Scientific Integrity Officials" with responsibility to "champion" scientific integrity, "provide oversight for the implementation" of the policy, and "act as liaisons for their respective Programs and Regions," but no apparent authority for them to actually do anything. Months of work on the guidance did not enable EPA to eliminate useless, circular language.[30] EPA says the policy repeats guidance issued by the Agency in 1999,[31] so it's not clear whether it contains anything new. In any case, EPA states that the policy is unenforceable by any entity other than EPA itself,[32] so this may not be a distinction with any difference.

In other respects, however, EPA's policy is much worse than the OSTP guidance. Like OSTP, EPA does not acknowledge the scientization of policy as a deficit in scientific integrity. Unlike OSTP, however, EPA's policy statement is not benign: it requires adherence to certain previously issued Agency guidelines whose very purpose is to scientize policy.[33] Why include this particular reference in scientific integrity guidelines? It ensures that the scientization of policy is exempt, while simultaneously making it appear that Agency officials "politicize science" if they ever try to reclaim the authority

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[28] U.S. Environmental Protection Agency (2010b), p. 4.

[29] Ibid. p. 1.

[30] See, e.g. Ibid. p. 3 ("To support a culture of scientific integrity within the Agency, this policy … [p]romotes a culture of scientific integrity").

[31] Ibid.

[32] Ibid. p. 2: The Scientific Integrity Policy "does not create any obligation, right or benefit for any member of the public, substantive or procedural, enforceable by law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees or agents, or any other person."

[33] Ibid. p. 4 (requiring adherence to EPA's Guidance for Risk Characterization).

delegated by Congress to make policy decisions that are now made "scientifically" by career staff.

Finally, EPA's scientific integrity policy includes an extensive section "[t]o assure the protection of Agency scientists," presumably from interference by Agency officials.[34] Notice that there is no parallel section protecting Agency officials from interference by Agency scientists in the exercise of their statutory authorities.

4. A recent joint report from the EPA's Science Advisory Board and Board of Scientific Counselors recommended that the Agency "include sustainability in its research vision" in order to allow "EPA to adopt sustainability as a core principle to inform decisions and actions." Is this emphasis on sustainability appropriate for EPA's research and science activities? Do you have any concerns about this new mission?

A comprehensive review of the SAB and BOSC foray into "sustainability" must await a clear definition of the term. EPA's existing definition is highly subjective and too ambiguous to be measured.[35] When a goal is subjectively defined or cant be measured, it can never be shown that it hasn't been achieved and it's anybody's guess whether achieving it is even a good thing.

The joint SAB/BOSC letter has similar difficulties. It recommends that EPA's Office of Research and Development

> include sustainability explicitly in its research vision, invoke a definition of sustainability shared across ORD, and demonstrate clearly how planned research relates to the key components of sustainability (the environment, the economy, and society).[36]

In lieu of a coherent definition, SAB/BOSC point to a recent National Research Council report, which also lacks a clear definition.[37] The NRC committee's review, which EPA sponsored, begins with numerous additional caveats. For example, the committee did not examine whether

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[34] Ibid. p. 5; Sec. IV(A)(3).

[35] U.S. Environmental Protection Agency (n.d.).

[36] U.S. EPA Science Advisory Board (2011), p. 6.

[37] National Research Council (2011), p. 3. "'Sustainability' and 'sustainable' mean to create and maintain conditions, under which humans and nature can exist in productive harmony, that permit fulfilling the social, economic, and other requirements of present and future generations."

"sustainability," so defined, is consistent with the statutes that govern EPA's authorized activities.[38]

It is always a concern when a Federal agency embarks on a new mission that is not explicitly authorized by law, and even more so when cheered on by scientists whose advice is sought primarily because they happen to embrace that mission. Public choice theory predicts that agencies will do this to expand their authority, power, staff, and resources. This is particularly characteristic of agencies such as EPA that have largely achieved the statutory objectives Congress originally assigned to it. Like private firms, agencies strive to reinvent themselves, including the creation of new missions, when it becomes clear that the need for their goods or services has dwindled, or they have become irrelevant or overcome by technological change. Federal agencies differ, however, insofar as they have no constitutional role to engage in activities that Congress has not authorized.

This suggests an inherent weakness in both the SAB/BOSC and NRC reports, and of course EPA's approach as well. Both reports could have, but did not, examine the extent to which the complicated and sometimes inconsistent patchwork of statutes that EPA implements has the perverse effect of making it harder for "humans and nature [to] exist in productive harmony." An obvious example might be the regulation of criteria air pollutants; the Clean Air Act can be interpreted to require the $PM_{2.5}$ and ozone NAAQS to be set at zero, in which case the statute is a suicide compact for humans and nature alike.

5. There was some discussion about the importance of objectivity and the role of peer review in EPA risk assessments.

a. Please describe how greater objectivity in assessments can be achieved, and what the practical effects of these improvements would be.

Among the witnesses testifying before the Committee on February 3, there appeared to be universal agreement that objectivity is not optional in science. Objectivity is an essential attribute of the scientific method, one that

[38] Ibid. pp. 17-18. The NRC committee attempts to show that Congress authorized EPA to implement sustainability via the National Environmental Policy Act of 1969. This logic is circular. NEPA did not establish "sustainability" as a governing principle; rather, President Obama borrowed hortatory language from NEPA to define "sustainability," whose definition the NRC committee then used. See Obama (2009a), p. 52126. Sec. 19(l).

is required via government-wide and EPA information quality guidelines.[39] Sometimes, objectivity (or one of its synonyms, "accuracy") is explicitly required by law.[40]

The hearing did not effectively distinguish between "science" and "risk assessment," however. EPA risk assessments are routinely described as scientific, even by Agency officials.[41] This is not correct. EPA risk assessments are notoriously lacking in objectivity, and as I testified before the Committee, this is a matter of design, not accident.[42]

Objectivity in risk assessment would serve three crucial purposes that current practices do not. First, it would ensure that EPA officials, Congress, and the public had unbiased information about the risks within EPA's jurisdiction. Second, it would enable these risks to be ranked so that resources devoted to risk reduction could be rationally allocated. Third, the authority to make risk management decisions that Congress has delegated to Agency officials would finally be made by those Agency officials, not by Agency scientists and career program managers with strong policy views.

b. Please describe the different types of peer reviews that science funded by or used by EPA may be subjected to, including which areas raise the most concerns.

As I have noted elsewhere in these replies and in my written testimony, peer review takes several different forms. Moreover, the purpose of scholarly peer review (to ration scarce journal pages) is fundamentally different than the purpose of governmental peer review (to ascertain what is correct). The procedures used for the former are ill-suited for the latter. For this reason, too much emphasis has been placed on scholarly peer review.

EPA peer review is governed by OMB guidelines and EPA's Peer Review Handbook, which have useful features but serious limitations and defects, as I have already discussed. To recap, these include too much Agency influence

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[39] Office of Management and Budget (2002), U.S. Environmental Protection Agency (2002).

[40] See, e.g., Clean Air Act, Sec. 108(a)(2): "Air quality criteria for an air pollutant shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities" (emphasis added).

[41] See, e.g., Anastas (2011), oral testimony.

[42] Belzer (2012), p. 5.

over the selection of reviewers and absolute control over their charge. EPA's peer review process is designed to maximize concordance with EPA's policy objectives. Finally, peer reviews of EPA risk assessments are suffused with risk management policy judgments.

In my testimony, I recommended that EPA peer reviews be strictly limited to science. I also suggested other reforms to the process, such as giving the most knowledgeable researchers on a scientific issue the responsibility of educating peer reviewers and coordinating open debate in which the public could actively participate. Unlike EPA practice, peer reviewers would never be drawn from the ranks of researchers who have published research or taken positions on the specific issue.

QUESTIONS FROM REP. RANDY NEUGEBAUER

1. ***What type of research does the EPA currently conduct to confirm predicted health outcomes of previously promulgated rules? In what ways can we improve existing efforts to examine the real effects of EPA rules, and what else can the Agency be doing to increase accountability for health and environmental predictions?***

I am not aware of any significant EPA effort to confirm predicted health outcomes for previously promulgated rules. The closest thing I can think of is EPA's reconstructions of the benefits and costs of the Clean Air Act, as it was required to do under Section 812.[43] These reports do not confirm anything, except perhaps the foolishness of asking an agency to conduct its own performance evaluation.[44]

If Congress is serious about estimating how actual health outcomes compare with predictions, it must ensure that the review is conducted rigorously, independently, and transparently. Not only does this exclude EPA from performing the review, it also excludes the National Academy of

[43] See most recently, U.S. Environmental Protection Agency (2011).

[44] For a review of EPA's first foray into self-examination in this area, see Lutter and Belzer (2000).

Sciences, which does not practice transparency in the selection of experts,[45] committee deliberation,[46] or internal peer review.[47]

2. Are there any legitimate concerns about making public the data sets that attempt to justify EPA regulations? Are there real concerns about confidentiality, and if so, do they outweigh the necessity of accountability, transparency, and open and sound scientific examination?

There are only two areas in which confidentiality is a legitimate concern in human health risk assessment. The first involves confidential business information, such as perhaps studies performed on proprietary mixtures. I am unaware of any serious controversies in this area, but they may exist.

The second involves personally identifiable information, which epidemiologists long ago learned how to anonymize. It is an exceedingly rare study in which the identity of subjects must be known by the researchers and statisticians analyzing the data. Usually, knowledge of subjects' identities, whether they belong to a case or control group, and similar matters are purposely hidden from researchers themselves to ensure objectivity.

Researchers often desire not to disclose their data because they consider it their own intellectual property. The case for this is very weak when the data collection was publicly funded, but strong otherwise. In my testimony, I offered a straightforward solution: EPA should be required to fully disclose any data it intends to rely upon for risk assessment or any component thereof. Disclosure of federally-funded research, to which the government already has a right, would be mandatory if the study met this condition. Similarly, any third party that wants EPA to rely upon its data would have to meet the same disclosure standard.

My approach would impose no involuntary burden on researchers, federal or otherwise. Researchers could decide whether to restrict access to their data or influence public policy, but they no longer would be allowed to

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[45] The National Academies (2003), The National Academies (2005), p. 6.

[46] The National Academies (2005), p. 10. "Committee meetings, particularly as the committee gathers information, are usually open to interested individuals and the news media. However, meetings are closed when the committee is deliberating to develop its findings and during discussion of financial and personnel matters. Closed meetings are not open to the public or to any person who is not a committee member or an official, agent, or employee of the Academies."

[47] The National Academies (2008).

do both. Full disclosure must be the price for seeking to influence public policy, regardless of the source of funding.

QUESTIONS FROM REP. PAUL TONKO

1. Private Consulting.

Prior to the February 3rd EPA E&E Subcommittee hearing, Ranking Member Mr. Miller asked you to provide a list of the clients for whom you conduct private consulting work that may have an interest in the subject matter of that hearing. You declined to identify any of your past or present clients because you claimed a "confidentiality agreement" exists between you and your clients and that providing this basic information would violate that agreement. It is my understanding that the majority of "confidentiality agreements" revolve around the specific issues that a 'client' hires a 'contractor' to perform, particularly the results of that work. It is less common that a "confidentiality agreement" would bar from public disclosure the mere fact that a business relationship exists between a client and a contractor.

- ***Please list all clients you have signed a confidentiality agreement with broadly related to the subject of environmental science and/or regulatory issues over the past five years.***

The public disclosure of the existence of a confidential relationship would be tantamount to breaching its contents. As I said in my reply to Ranking Member Miller, I intend to honor these agreements and thus respectfully decline to identify past and present clients.

It is clear from information already in the public domain that you worked for the U.S. Department of Defense, through a consulting agreement with Booz Allen Hamilton; advising DOD on issues revolving around the chemical Perchlorate in 2003 and 2004.

- *Please indicate if you still have a business relationship with Booz Allen Hamilton and/or DOD? If not, please indicate when that relationship ended?*

I do not have a current business relationship with Booz Allen Hamilton and/or DoD. I believe that my previous relationship ended in April 2005.

2. Public Disclosure.

At the Feb. 3rd hearing you said: "When I do things that are public, when I put my name on something, a piece of work that I've produced then I disclose who I did it for." It was unclear from your response, however, what work products you consider to be "public".

- ***Please provide a list of work products you have produced over the past five years where you publicly disclosed who you did this work for, as you indicated you had done in your congressional testimony. Please include the title or name of the work product, the client's name you performed the work for, and where and when this work was presented or appeared.***

I have uploaded to my personal website at www.rbbelzer.com every publication, presentation, public comment, or similar work product that I have been able to locate—peer-reviewed or otherwise. For work products that are covered by a copyright owned by someone else, I provide links to web sites where copies can be purchased. I also have disclosed documents I authored on behalf of the Federal government.

Some of this work pre-dates the Internet era, however, so my website is regrettably incomplete.

REFERENCES

Allison G. 1971. Essence of Decision: Little Brown.

Anastas P. 2011. *Written Testimony Before the U.S. House of Representatives Committee on Science Space and Technology, Subcommittee on Oversight, Hearing on 'EPA's Integrated Risk Information System'*. [July 14]; http://science.house.gov/sites/republicans.science.house.gov/files/documents/hearings/071411_Anastas.pdf.

Belzer RB. 2002. *Interests and Incentives in Government Peer Review*. "Conflict, Consensus, and Credibility: A Forum on Regulatory Peer Review". Alexandria, Va.: Society for Risk Analysis [May 29, 2002]; http://www.rbbelzer.com/presentations.html - 2002.

Belzer RB. 2012. *Testimony Before the Subcommittee on Energy and the Environment, Committee on Science, Space, and Technology, U.S. House of Representatives, Hearing on "Fostering Quality Science at EPA: Perspectives on Common Sense Reforms—Day II"*. [February 3].

Bipartisan Policy Center. 2009. *Improving the Use of Science in Regulatory Policy*. Washington, D.C.: Bipartisan Policy Center [August 5]; http://www.bipartisanpolicy.org/sites/default/files/BPC Science Report fnl.pdf.

Holdren JP. 2010. *Memorandum for the Heads of Executive Departments and Agencies: Scientific Integrity*. Office of Science and Technoloy Policy; http://www.whitehouse.gov/sites/default/files/microsites/ostp/scientific-integrity-memo-12172010.pdf.

Lutter R, Belzer RB. 2000. EPA Pats Itself on the Back. *Regulation* 23(3): 23-28.

National Research Council. 2011. Sustainability and the U.S. EPA. Washington, D.C.: National Academies Press.

Obama B. 2009a. Executive Order 13514: Federal Leadership in Environmental, Energy, and Economic Performanc. *Federal Register* 74(194): 52117-52127 (http://edocket.access.gpo.gov/2009/pdf/E9-24518.pdf).

Obama B. 2009b. Scientific Integrity. *Federal Register* 74(46): 10671-10672.

Office of Management and Budget. 2002. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Notice; Republication. *Federal Register* 67(36): 8452-8460 (http://www.whitehouse.gov/omb/fedreg/reproducible2.pdf).

Office of Management and Budget. 2005. Final Information Quality Bulletin for Peer Review. *Federal Register* 70(10): 2664-2667 (http://www.whitehouse.gov/omb/fedreg/2005/011405_peer.pdf).

Office of Management and Budget. 2007. Final Bulletin for Good Guidance Practices. *Federal Register* 72(16): 3432-3440 (http://www.whitehouse.gov/omb/assets/regulatory_matters_pdf/m07-13.pdf).

The National Academies. 2003. *Policy on Committee Composition and Balance and Conflict of Interest*. The National Academies [May 12].

The National Academies. 2005. *Getting to Know the Committee Process*. Washington, D.C.: The National Academies; http://www.nationalacademies.org/nrc/CommitteeProcess.pdf.

The National Academies. 2008. *Guidelines for the Review of National Academies Reports*. Washington, DC: National Research Council, Report Review Committee.

U.S. Environmental Protection Agency. 2002. *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency (EPA/260R-02-008)*. http://www.epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf.

U.S. Environmental Protection Agency. 2006. *Peer Review Handbook (3rd Ed.)*. Washington, D.C.: U.S. Environmental Protection Agency Science Policy Council; http://www.epa.gov/peerreview/pdfs/Peer Review HandbookMay06.pdf.

U.S. Environmental Protection Agency. 2009. Regulatory Agenda #142. Reconsideration of the 2008 Ozone National Ambient Air Quality Standards. *Federal Register* 74(233): 64327 (http://www.gpo.gov/fdsys/pkg/FR-2009-12-07/pdf/X09-181207.pdf).

U.S. Environmental Protection Agency. 2010a. National Ambient Air Quality Standards for Ozone; Proposed Rule. *Federal Register* 75(11): 2938-3052.

U.S. Environmental Protection Agency. 2010b. *Scientific Integrity Policy*```. Available: http://www.epa.gov/osa/pdfs/epa_scientific_integrity_policy_20120115.pdf [accessed March 3, 2012].

U.S. Environmental Protection Agency. 2011. *The Benefits and Costs of the Clean Air Act from 1990 to 2020; Final Report – Rev. A*. Washington, D.C.: U.S. Environmental Protection Agency.

U.S. Environmental Protection Agency. n.d. *Sustainability; Basic Information; What is is Sustainability?* Available: http://www.epa.gov/sustainability/basicinfo.htm - sustainability [accessed March 3, 2012].

U.S. EPA Science Advisory Board. 2011. *Office of Research and Development (ORD) New Strategic Research Directions: A Joint Report of the Science Advisory Board (SAB) and ORD Board of Scientific Councilors (BOSC)*. Available: http://yosemite.epa.gov/sab/sabproduct.nsf/804D1A3A4A393C028525793000732744/$File/EPA-SAB-12-001-unsigned.pdf [accessed March 3, 2012].

Responses by Dr. Jerald Schnoor,
Allen S. Henry Chair in Engineering,
Department of Civil and Environmental Engineering,
University of Iowa

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

Hearing Questions for the Record
The Honorable Andy Harris

Fostering Quality Science at EPA: The Need for Common Sense Reform Day II
February 3, 2012

Dr. Jerald Schnoor

1. The Bipartisan Policy Center's 2009 report, "Improving the Use of Science in Regulatory Policy" was mentioned during the hearing. This report made several suggestions that may be useful in guiding this Subcommittee's efforts to reform regulatory science, including:

   - "Studies used in the formulation of regulation should be subject to data access requirements equivalent to those under the Data Access Act."
   - "The process of conducing literature reviews" and "the process of naming advisory committees" should be made more transparent.
   - "Agencies should avoid turning repeatedly to the same scientists for service on advisory committees."
   - Executive branch agencies need to "help clarify for both officials and the general public which aspects of disputes are truly about scientific results and which concern policy."
   - "Policy makers should be wary of conclusions of risk that are expressed as a single number."
   - "Federal agencies need to experiment with ways to increase the number of scientists who participate in peer review."
   - "In presenting the conclusions of literature reviews, agencies and their scientific advisory committees need to be as open and precise as possible in discussing levels of risk and uncertainty."

   Do you agree with any or all of these recommendations? Do you have any additional comments or advice in pursuing these goals?

   I went to the Bipartisan Policy Center's website and found that this 2009 report was listed as an "interim report". I could not download the report from their site, so I was not able to read about these recommendations. It is difficult to comment without having the context of the recommendation. However, I would state that during my past service to EPA Board of Scientific Counselors, EPA Science Advisory Board, NIEHS Advisory Council, and National Research Council/National Academies of Science, I have not become aware of problems associated with these points. I believe the process of naming advisory committees is quite transparent, that advisory committee members are regularly rotated, that most reports try to include an estimate of uncertainty, and that the Federal Advisory Committees Act (FACA) requires openness (by law). Regarding the distinction

between science and policy recommendations, it is usually clear whether the committee is commenting on science or policy. Many times, advisory committees are specifically asked to critique or evaluate policy. In addition, research in the social sciences (social/behavioral/decision sciences, including economics) often comprises "policy research", and the distinction is sometimes blurred.

2. In discussing problems with the EPA Science Advisory Board process, Mr. Walls noted that "qualified scientists from industry should be given equal consideration" to serve on advisory panels. Do you support that recommendation?

I do not support quotas, but I do support inclusion of members from industry along with other groups. I think EPA tries to attract qualified scientists from industry for the SAB and other Boards, but sometimes it is difficult for these scientists to afford the time to serve. It would be desirable to have more scientists from industry, I think.

A good advisory committee should include members who have distinguished themselves as leaders in the field by virtue of their publications, citations, patents, awards and recognition. They should embody a diversity of backgrounds, affiliations, expertise, experience, and viewpoints. Industry scientists should certainly be among the experts considered and selected. I have not served on an advisory committee in my memory which did not include members from industry. Experts from NGOs, academia, business, industry, and government should all be considered.

3. Many EPA science activities are housed within regulatory offices. For example, nearly half of EPA's laboratories do not reside in the Office of Research and Development. In your view, should scientific activities be organizationally insulated from regulatory activities to ensure objectivity and balance?

No, I do not believe that one should "organizationally insulate" scientific from regulatory activities in EPA. On the contrary, I would like to see better coordination of science to achieve the policy mission of EPA throughout the Agency. Better coordination is needed to leverage scientific research among ORD, Agency Offices (Water, Air, Radiation, etc.), Regional Offices, and the States/Tribes/Nations. The mission of EPA is to protect human health and the environment from pollution and other agents. Quality science is needed to inform the policy decisions within the Agency for that protection at all levels.

4. In an August 2010 editorial in the journal Environmental Science and Technology titled "Regulate, Baby, Regulate", you asserted that hydraulic fracturing associated with shale gas development was "causing tap water to burn." Please provide evidence to support this assertion and describe how they relate to the standards employed by the publication in ensuring accuracy and appropriate communication of scientific uncertainties in journal editorials.

In the editorial, I was referring to the documentary *Gasland* regarding the phrase "causing tap water to burn". But, indeed, the problem may emanate from improperly constructed or maintained wells on the part of both homeowner and industry. Osborn et al. (2011) in the

Proceedings of the National Academy of Sciences (doi:1073/pnas.1100682108) article, "Methane contamination of drinking water accompanying gas-well drilling and hydraulic fracturing", found that 51 of 60 homeowner wells within one kilometer of new natural gas wells were contaminated with deep methane of shale origin in the Marcellus and Utica shale formations of northeastern Pennsylvania and upstate New York. Corresponding author, Robert B. Jackson, Duke University, said, "I saw a homeowner light his water on fire – the biggest risk is flammability and explosion" (http://www.scientificamerican.com/article.cfm?id=fracking-for-natural-gas-pollutes-water-wells&print=true).

The PNAS article is by no means the last data on the subject. Certainly, there is more to learn about how contamination of wells may occur. And there are follow-up studies being undertaken, including one by EPA. But it is clear that gas wells must be properly constructed, maintained, and plugged after operation. Such diligence will require careful regulation on the part of EPA. Fracking chemicals should be made known to EPA; the public's safety over-rides the need for proprietary privilege here. Furthermore, wells should be plugged and radioactive contaminants in pits, ponds and lagoons from fracking operation return flows must be treated or otherwise reinjected.

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

Hearing Questions for the Record
The Honorable Randy Neugebauer

Fostering Quality Science at EPA: The Need for Common Sense Reform Day II
February 3, 2012

Dr. Jerald Schnoor

1. What type of research does the EPA currently conduct to confirm predicted health outcomes of previously promulgated rules? In what ways can we improve existing efforts to examine the real effects of EPA rules, and what else can the Agency be doing to increase accountability for health and environmental predictions?

Further studies are needed to confirm that human health and ecosystems improve following new regulations – I will call such studies "post-audits". But these post-audits will be expensive and funding will be required. In my written testimony delivered on February 3, 2012, I mentioned an example of follow-up studies that were made to the Harvard Six Cities epidemiologic report by Dockery et al (1993), which first implicated the role of fine particles ($PM_{2.5}$) in morbidity and mortality from air pollution. There remained questions about the etiology of the disease and the surprising results of cardiopulmonary deaths, so follow-up studies (post-audits) were undertaken. In 2000, a reanalysis of the Harvard Six Cities Study was reported by the Health Effects Institute (HEI) and, in 2004, research was completed that validated the initial results (Krewski et al., 2004). An extended follow-up study by Francine Laden and colleagues was subsequently published in 2006 (Laden et al, 2006) as well as a summary of the beneficial effects on life expectancy by Pope et al. (2009). Laden was quoted in a Harvard School of Public Health Press Release at the time:

"The follow-up study found that an average of three percent fewer people died for every reduction of one microgram per cubic meter in the average levels of PM2.5 fine particulate matter, defined as having a diameter of 2.5 microns or less – narrower than the width of a human hair. This decreased death rate is approximate to saving 75,000 people per year in the U.S."

That's an example of the scientific process performing well. A hypothesis was tested, results obtained, questions arose, and further studies were undertaken to confirm the results. Continual challenges to a standing theory or hypothesis are recorded in the scientific literature. Each research article must pass rigorous peer review, and subsequent studies either confirm the initial results or posit a new theory. The theory stands until future studies disprove it (if ever). That is how the body of knowledge grows.

2. Are there any legitimate concerns about making public the data sets that attempt to justify EPA regulations? Are there real concerns about confidentiality, and if so, do they outweigh the necessity of accountability, transparency, and open and sound scientific examination?

Transparency of scientific results serves the public's best interests. However, sometimes it is difficult or even impossible for an individual scientist to respond to all the requests that s/he may receive. They may not have the resources or time required to respond. But, regardless, their data should be made available to the public through the journal in which it was published. Other investigators need the original data because they may attempt to reproduce the study. Of course, the names and identities of individuals in the data set may be confidential as required by federal law in the case of health studies and personal information (HIPAA, FERPA).

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

Hearing Questions for the Record
The Honorable Brad Miller

Fostering Quality Science at EPA: The Need for Common Sense Reform Day II
February 3, 2012

Dr. Jerald Schnoor

EPA ORD Realignment

1. In the realignment of the Office of Research and Development programs you both described in your testimony, has the reduction and integration of the number of programs down from 13 to 6, proven to be a more efficient and effective strategy for EPA-ORD research activities? How has this alignment improved ORD's coordination with the program and regional offices? What more can and needs to be done to strengthen the EPA overall research enterprise?

   It is a bit early to determine if the realignment of EPA ORD programs has been successful because it is just being undertaken in 2012. However, I believe the restructuring makes sense -- it was in concert with advice provided in recent years by both the Science Advisory Board (SAB) and the Board of Scientific Counselors (BOSC). Thirteen major programs proved somewhat unwieldy, and the proposed realignment received positive review from the SAB (SAB, 2011). Motivation for this consolidation and realignment of programs reflects an emphasis on integrated trans-disciplinary research, multi-pollutant exposures, and sustainability. These are not new programs, but represent a new way of thinking within ORD. Considerable synergies may be realized in combining research into the four programmatic areas: Air, Climate and Energy; Safe and Sustainable Water Resources (water quality plus drinking water); Sustainable and Healthy Communities; and Chemical Safety for Sustainability; plus two smaller programs in Homeland Security Research and Human Health Risk Assessment. ORD is evolving from a risk management paradigm, which has guided and influenced research over the past two decades, towards a sustainability paradigm. That effort will likely pay dividends. It is consistent with a public health approach of "preventing disease" rather than a medical approach to "treating disease" after it occurs, and it recognizes that environment and health are an interconnected system. It also follows from early pioneering research at EPA on Pollution Prevention at the source, rather than end-of-pipe.

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

Hearing Questions for the Record
The Honorable Andy Harris

Fostering Quality Science at EPA: The Need for Common Sense Reform Day II
February 3, 2012

Dr. S. Stanley Young

1. The Bipartisan Policy Center's 2009 report, "Improving the Use of Science in Regulatory Policy" was mentioned during the hearing. This report made several suggestions that may be useful in guiding this Subcommittee's efforts to reform regulatory science, including:

   - "Studies used in the formulation of regulation should be subject to data access requirements equivalent to those under the Data Access Act."
   - "The process of conducting literature reviews" and "the process of naming advisory committees" should be made more transparent.
   - "Agencies should avoid turning repeatedly to the same scientists for service on advisory committees."
   - Executive branch agencies need to "help clarify for both officials and the general public which aspects of disputes are truly about scientific results and which concern policy."
   - "Policy makers should be wary of conclusions of risk that are expressed as a single number."
   - "Federal agencies need to experiment with ways to increase the number of scientists who participate in peer review."
   - "In presenting the conclusions of literature reviews, agencies and their scientific advisory committees need to be as open and precise as possible in discussing levels of risk and uncertainty."

   Do you agree with any or all of these recommendations? Do you have any additional comments or advice in pursuing these goals?

2. In discussing problems with the EPA Science Advisory Board process, Mr. Walls noted that "qualified scientists from industry should be given equal consideration" to serve on advisory panels. Do you support that recommendation?

3. Dr. Schnoor's testimony cites work done on the link between fine particulate matter (PM) and premature mortality by Dr. Francine Laden, including the claim that PM-related regulations had saved more than 75,000 lives, as "an example of quality science performing well." Have you examined this literature based on epidemiological studies, and, if so, do you find it rigorous enough to justify major, costly EPA regulations?

4. Some people have expressed concerns about the practical effects of making underlying data sets publically available, citing significant costs and concerns about confidentiality. Are these concerns valid? Why or why not? To the extent you believe such concerns are valid, how might they be addressed to minimize potential negative impacts of making data publicly available?

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Dr. S. Stanley Young

1. What type of research does the EPA currently conduct to confirm predicted health outcomes of previously promulgated rules? In what ways can we improve existing efforts to examine the real effects of EPA rules, and what else can the Agency be doing to increase accountability for health and environmental predictions?

2. Are there any legitimate concerns about making public the data sets that attempt to justify EPA regulations? Are there real concerns about confidentiality, and if so, do they outweigh the necessity of accountability, transparency, and open and sound scientific examination?

Responses by Dr. S. Stanley Young,
Assistant Director for Bioinformatics,
National Institute of Statistical Sciences

Questions Dr. Young

In general I fully support the statements in Question 1. What follows are specific comments to parts of that question.

Bullet #3. "Agencies should avoid turning repeatedly to the same scientists…"
I would strengthen this in the following way. Scientists should serve for no longer than 3-years terms and not be eligible for re-appointment for 3 years after serving. If service is expected to be a public service, it should not be turned into a method to secure government grants.

Congressman Joe Barton commented: "Almost every single member of your Clean Air Science Advisory Committee (CASAC) has been directly or indirectly funded for research." According to Steve Milloy, examination of the EPA extramural grants data base, found that members had research grants from the EPA:

- CASAC chairman **Jonathan Samet** is listed a principal investigator on $9,526,921 in EPA grants.
- Board member **George Allen** received is listed as a principal investigator on $3,907,111 in EPA grants.
- Board member **Ana Diez-Roux** is listed as a principal investigator on $31,343,081 in EPA grants.
- Board member **H. Christopher Frey** is listed as a principal investigator on $2,956,342 in EPA grants.
- Board member **Armistead Russell** is listed as a principal investigator on $20,130,736 in EPA grants.
- Board member **Helen Suh** is listed as a principal investigator on $10,962,364 in EPA grants.
- Board member **Kathleen Weathers** is not listed as a principal investigator on any EPA grants; but her employer, the Cary institute of Ecosystem Studies, is listed as a the lead institution in $3,570,926 in EPA grants.

Bullett #5 "Policy makers should be wary…"
It is a problem if policy is decided and then supporting science is sought. It is not just a summary into one number, which is a problem. Any justification of a regulation should list the science papers that support a policy and those that oppose the policy.

A single number can be misleading. For example, a cost benefit ratio can be 5 where we have $5/$1=5 (trivial), or $5B/$1B (having major impact). Papers justifying both numerator and denominator should be provided.

Bullett #6 "Federal agencies should experiment …"
Peer review of agency science or actions is not enough to ensure validity of agency work. One way to expand oversight is to require that data used in papers that the agency is relying on is public. Specifically, the agency should identify important papers, papers

being used to help justify policy decisions, data used in these papers should be secured, electronic (easily readable and ready for analysis) copies of this data should be posted on the agency web site.

If the agency is funding work, then it should seriously consider funding data collection, staging and posting separately from data analysis. The group collecting the data should in no sense "own" the data. The data should be a public good.

If the data is public, then the whole scientific process can be used for peer review.

Question 2. "...qualified scientists from industry..."
Scientists do not live in a financial vacuum. University scientists compete for grants and industrial scientists work to advance their company. Hopefully data and methods will lead both to sound conclusions. If government funded scientists are allowed to participate, so should industrial scientists.

Questions 3. "... link between ...PM and premature mortality..."
I have examined this literature to some degree. For acute deaths, if a person is going to die within two weeks and they die sooner by a few days rather than later in a few weeks has a life been saved? Most of the literature I have read is not capable of addressing this issue. For long-term deaths, environmental epidemiology is not capable of reliably detecting effects as small as those observed. The risk ratios at issue, less than 1.5 and often as small as 1.05, could easily be the result of some bias in the data.

Two recent papers, Laden et al. (2007) and Birdsey et al. (2011), of diesel give conflicting claims. Neither paper observes an increase in all-cause mortality due to diesel exposure; both appeal to the "healthy worker effect". Laden et al. (2007) claim an increase in lung cancer, but the confidence limits overlap 1.00 so most would not consider their evidence compelling. There is also a claim an increased heart disease with a RR of 1.41. Birdsey et al. (2011) find neither an increase in lung cancer nor any effect on heart disease.

Birdsey et al. comment: "Previous research suggests that truck drivers are at increased risk for lung cancer ..., prostate cancer ... heart disease, hypertension...,stomach ulcers ..., bladder cancer, and stomach cancer."

but find with their data set that

"Mortality was not increased for any of the health conditions previously shown to be elevated among truck drivers ..., although the lack of statistically significant estimates for cancers of the stomach, bladder, and prostate indicates that excess mortality from these causes cannot be totally eliminated (Table 3)." Note that Laden et al. do not confirm previous claims. Bias, multiple testing and multiple modeling are likely all at play, and as Koop et al, cited later, indicate, findings from observational environmental studies can be unreliable.

Some, e.g. Laden, make a claim for a very small effect and then multiply their small risk times the US population to make a claim for a large number of statistical deaths. Claims coming from epidemiology studies are notoriously unreliable, Young and Karr (2001). In the case of the Laden claims against diesel are not supported by Birdsay. Neither Laden nor Birdsay find any effect on mortality for truck drivers.

A recent paper where Laden is a co-authors states, "Conclusions: Among this cohort of men with high socioeconomic status living in the midwestern and northeastern United States, the results did not support an association of chronic PM exposures with all-cause mortality and cardiovascular outcomes in models with time-varying covariates." So Laden appears to be on both sides of the air pollution and mortality question.

A recent press release from the EPA made a claim of 160,000 lives saved in 2010. Again, very small and quite variable risk estimates are multiplied by the size of the US population. The risk estimates are all well within the range of study bias. The press release also makes a claim for preventing more than 170,000 asthma attacks. The Koop et al.(2010) and therefore calls those claims into question as they saw no increase in hospital admissions for asthma related to air pollution.

Birdsey J, Alterman T, Li J, Petersen MR, Sestito J. Mortality among members of a truck driver trade association. *AAOHN Journal* 2010. 58, 473-480.

EPA Press Release
http://yosemite.epa.gov/opa/admpress.nsf/7ebdf4d0b217978b852573590040443a/f8ad3485e788be5a8525784600540649!OpenDocument

Koop G, Ross McKitrick R, Tole L. Air pollution, economic activity and respiratory illness: Evidence from Canadian cities, 1974–1994. *Environmental Modelling & Software* 2010 25, 873–885.

Laden F, Hart JE, Smith TJ, Davis ME, Garshick E. (2007). Cause-specific mortality in the unionized US trucking industry. *Environmental Health Perspectives.* 2007. 115, 1192-1196.

Puett RC, Hart JE, Suh H, Mittleman M, Laden F. (2011) Particulate matter exposures, mortality, and cardiovascular disease in the Health Professionals Follow-up Study. *Environ Health Perspect* 119:1130–1135.

Young SS, Karr A. Deming, data and observational studies, a process out of control and needing fixing. *Significance.* September2011, 116-120.

Question 4. Cost of making data available

Data is collected, then staged into an "analytical data set" suitable for statistical analysis. The collection and staging of data is expensive, but it has to be done for any published paper. The cost of making this analytical data set electronically available is typically

quite low. With planning, meta data describing the analytical data set is also inexpensive to produce. One to a few sentences can be given to instruct another analyst what the variables mean. There is a NSF funded data repository, see datadryad.org, where the analytical file and the meta data can be deposited, which removes the burden or responding to individual data requests. In short, once data is staged to be used in a publication, the incremental cost of making data available is low.

General Comments:
Question from Chairman Harris, "What is the EPA doing in their R&D budget to look at whether or not these health benefits that are claimed actually come to pass in the magnitude that they are claimed?"
Answer: One of the supposed strengths of science is that over time replication of results gives results credence. There is a premium in science for being first with a claim and also journals favor new results, not replication of results. The agency could and should fund studies attempting to replicate important claims. In the area of medical observational studies, claims most often fail to replicate. See Young and Karr (2011). Ioannidis, JAMA, (2005) notes that 5/6 claims coming from medical observational studies failed to replicate or the claimed size of the effect was greatly reduced. The agency should identify important claims and fund independent studies to determine if the claims replicate. For example, do claimed mortality affects of PM2.5 in the East replicate in the West? Do claimed effects during the time 1990-1999 replicate during the time 2000-2009? Note that making data available at the time of publication of a paper would greatly speed up the scientific evaluation of the claims made in the paper.

Mr. Greenbaum notes that scientists within the agency are both "creating some science but they are then involved in the interpretation of that science." A clear separation of data collection and staging from data analysis and interpretation would help the scientific process. For example in a FDA supervised clinical trial, the statistical analysis is pre-specified. Data is collected and staged. Finally the cleaned data is given to statisticians for analysis. The data is also given to the FDA. No one group is responsible for all steps in the process. Ioannidis, JAMA, 2005, notes that claims coming from randomized clinical trials replicate over 80% of the time. Administrative procedures can be put in place to support normal science. Make data sets publicly available on the publication of a paper. To verify important claims, independent studies should be funded. Separate data collection and staging from analysis and interpretation. Etc.

Correction: Line 1012. Change "data." to "paper."

Line 1037 and again Line 1373. Mr. Schnoor makes the statement, "As a journal editor, our policy is, and most journals, that if the data is asked for, we do give it." It is a fact that most journals do not require that authors make their data available as a condition of publication. Science, Nature, PNAS are exceptions. Even when authors sign agreements to make data available, most often they do not. About 2/3s of the time, data asked for is not provided. One solution would be to require the data files used in analysis be deposited with the journal or a data repository, datadryad.org.

Line 1204ff. "Is the science conducted, in your opinion, by the EPA generally of poor quality?"
Answer: We really do not know the quality of their work for several reasons:

1. Strictly internal work is not subject to independent peer review.
2. Papers they publish are subjected to peer review, but peer review most typically does not examine the data set and reanalyze it. Peer review only says that paper meets the general standards of the area. Note well: for observational studies claims most often do not replicate, Young and Karr, 2011.
3. Much of the critical work of the EPA is via contract. EPA scientists do not necessarily get the data sets (as the FDA would) and they do not do an independent re-analysis of the data.

We are largely observing "trust me" science. At best we have no idea of the quality of their work. At worst, claims coming from environmental epidemiology studies are no better than claims coming from medical observational studies. With medical observational studies claims fail to replicate 80 to 90% of the time, Ioannidis, JAMA, 2005 and Young and Karr (2011).

Line 1442 Mr. Greenbaum, "…we cannot have detailed re-analysis of every single paper…"

Answer: If the data is publicly available, then anyone with an interest can have a re-analysis computed. Support the normal working of science by making data public. For key claims, the agency should fund an independent re-analysis or indeed a new study. Remember, we are not working in an area where claims are generally reliable.

Appendix II

Additional Material for the Record

REPRINT FROM *American Journal of Entomology*:
"REPRODUCIBLE EPIDEMIOLOGIC RESEARCH"

American Journal of Epidemiology

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Advance Access publication March 1, 2006

Commentary

Reproducible Epidemiologic Research

Roger D. Peng, Francesca Dominici, and Scott L. Zeger

From the Biostatistics Department, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD.

Received for publication November 4, 2005; accepted for publication January 10, 2006.

The replication of important findings by multiple independent investigators is fundamental to the accumulation of scientific evidence. Researchers in the biologic and physical sciences expect results to be replicated by independent data, analytical methods, laboratories, and instruments. Epidemiologic studies are commonly used to quantify small health effects of important, but subtle, risk factors, and replication is of critical importance where results can inform substantial policy decisions. However, because of the time, expense, and opportunism of many current epidemiologic studies, it is often impossible to fully replicate their findings. An attainable minimum standard is "reproducibility," which calls for data sets and software to be made available for verifying published findings and conducting alternative analyses. The authors outline a standard for reproducibility and evaluate the reproducibility of current epidemiologic research. They also propose methods for reproducible research and implement them by use of a case study in air pollution and health.

air pollution; information dissemination; models, statistical

Abbreviation: NMMAPS, National Morbidity, Mortality, and Air Pollution Study.

Determinants of human disease are commonly investigated by epidemiologic studies focused on a particular subpopulation, time frame, and geographic location. Findings from such studies can play an important role in policy decisions affecting public health (1). Yet epidemiologic research has been criticized as being increasingly unreliable. One review of the field a decade ago raised questions about the reliability of observational epidemiologic studies when quantifying the health effects of important, but subtle, risk factors such as second-hand smoke, air pollution, and diet (2).

Scientific evidence is strengthened when important findings are *replicated* by multiple independent investigators using independent data, analytical methods, laboratories, and instruments. Replication, as described here, has long been the standard in the biologic and physical sciences and is of critical importance in epidemiologic studies, particularly when they can impact broad policy or regulatory decisions. Because of the time and expense involved with epidemiologic studies, many are often not fully replicable, and policy decisions must be made with the evidence at hand.

An attainable minimum standard is *reproducibility*, where independent investigators subject the original data to their own analyses and interpretations. Reproducibility calls for data sets and software to be made available for 1) verifying published findings, 2) conducting alternative analyses of the same data, 3) eliminating uninformed criticisms that do not stand up to existing data, and 4) expediting the interchange of ideas among investigators. Ultimately, all scientific evidence should be held to the standard of full replication and the confirmation of important findings by independent investigators. However, the desire to quantify small health effects and the significant weight placed on epidemiologic findings in the policy-making process create a need for epidemiologic studies to meet a minimum standard. We propose reproducibility to be this minimum standard.

There are a number of new developments that are intensifying the need for reproducible epidemiologic research.

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The signal-to-noise ratio in today's epidemiologic studies tends to be smaller than it was in decades past simply because much of the "low-hanging fruit" has been picked. Factors with large relative risks, such as smoking, socioeconomic status, family history, and obesity, are well established for major diseases. The targets of current investigations tend to have smaller relative risks that are more easily confounded. For example, in air pollution epidemiology, the national relative risk of increased mortality is estimated to be 1.005 per 10 parts per billion of 24-hour ozone. Remarkably, an integrated analysis of mortality in 95 metropolitan areas can detect this signal, which translates into thousands of excess deaths per year given the universality of ozone exposure (3). Nevertheless, the potential for unexplained confounding cannot be denied for such a small relative risk (4, 5).

The explosion of new biologic measurements presents exciting opportunities for epidemiologic studies. We can now quantify DNA sequences, single nucleotide polymorphisms, and gene and protein expression. We can image the structure and function of the brain and other organs. We can quantify diet with lengthy dietary-recall questionnaires and can quantify disease symptoms and health conditions with multiitem instruments. However, because the data are inherently complex and high dimensional, there is an increased potential for identifying spurious associations between their components and risk factors or health outcomes (6).

The widespread availability of statistical and computing technology is yet another factor contributing to the potential for false positive epidemiologic findings. It is now easy for a researcher to routinely engage in sophisticated optimizations across a large number of models and/or variables to identify associations that are of potential scientific interest. Even with a single risk factor and a single response, it is standard practice to consider a potentially large number of models in an effort to adjust for differences among the exposed and the unexposed. As the number of covariables measured increases, so do the degrees of freedom for influencing the association between the risk factor and outcome and for identifying subgroups in which the association is particularly strong.

The developments identified above also have the potential to increase the power and precision of epidemiologic research by enhancing our understanding of disease mechanisms and leading to studies with more targeted hypotheses. Modern computing makes possible the organization and analysis of large databases, so that we can look farther and wider for systematic patterns indicating the health effects of various risk factors. The reproducibility of epidemiologic findings from current and future studies will be crucial to providing the substance for informed debate regarding policies affecting the public's health.

DEFINING REPRODUCIBLE RESEARCH

Reproducibility is a minimum step that can be taken in any study. In the context of epidemiology, a study is reproducible when it satisfies the criteria in table 1, adapted from the paper by Schwab et al. (7) and others. We illustrate reproducibility requirements separately for each of the following research components: data, methods, documentation, and distribution.

TABLE 1. Criteria for reproducible epidemiologic research

Research component	Requirement
Data	Analytical data set is available.
Methods	Computer code underlying figures, tables, and other principal results is made available in a human-readable form. In addition, the software environment necessary to execute that code is available.
Documentation	Adequate documentation of the computer code, software environment, and analytical data set is available to enable others to repeat the analyses and to conduct other similar ones.
Distribution	Standard methods of distribution are used for others to access the software, data, and documentation.

Epidemiologic data sets can be difficult to define because of the complexity of the data collection and the preprocessing. In addition, a published finding may use only a subset of the data collected for a particular study, the other parts being irrelevant to the reproducibility of the finding. We therefore separate the data into "analytical" data, which serve as the input to a statistical analysis program to produce the results found in the table/figure supporting the paper's conclusions, and "measured" data, which consist of all data and functions thereof that are used to create the analytical data, whether or not they are part of the analytical data. This classification is crude and far from ideal, but it strikes a compromise between those data that are necessary for reproduction and those that may be of secondary interest. We propose as a first requirement that the analytical data set be made available to others for reproducing results.

With the increased use of advanced statistical methodology and larger data sets, analyses today are almost always implemented on a computer. Given that, the simplest way to reproduce the statistical methods is to examine the computer code or instructions for the analysis. While some analyses may be considered too rudimentary to warrant publishing computer code, most statistical software routines, for example, contain many options that need to be set by the user. Since it is not always clear from the outset which options can have an impact on the numerical results, this information can be critical for reproducing scientific findings, particularly when investigating small relative risks (8, 9).

REPRODUCIBILITY OF CURRENT EPIDEMIOLOGIC RESEARCH

To measure the reproducibility of recent epidemiologic research, we reviewed 90 epidemiology articles from the *American Journal of Epidemiology* and the *Journal of the American Medical Association*. We selected every article published in 2005 in the time period between January and the time at which we conducted the review (May). We developed a questionnaire to collect information relevant to

TABLE 2. Results from examining the epidemiologic literature: articles from the *American Journal of Epidemiology* and the *Journal of the American Medical Association* published between January 2005 and May 2005

	No. of papers
Total papers collected	90
Observational studies	69
Cross-sectional	20
Case-control	20
Cohort	29
Source of outcome data	
Original study	31
Ongoing study	29
Government	8
Other	1
Statistical analysis implementation	
Not reported	21
By hand	0
Use of software package	48
Method of processing measured data	
Not reported	43
By hand	1
Use of software package	13
Outcome data reported to be available	0
Exposure data reported to be available	1
Code for statistical analysis available	0
Code for processing measured data available	0

reproducibility that is available at http://www.biostat.jhsph.edu/~rpeng/reproducible/survey/. Some of the articles selected during this time period were excluded on the basis of the criteria developed in the questionnaire.

We focused our review of an article on the abstract's *concluding statement* summarizing the main scientific findings. Each statement contained information about an outcome and an exposure variable or risk factor, as well as potential confounders and/or effect modifiers. For a given article, we first determined the type of study: randomized trial, methodology, literature review or meta-analysis, or original observational study. The survey addressed only the last category, as it forms the bulk of epidemiologic research. Articles describing other types of studies were excluded. Given an observational study, we determined the study design, the primary outcome and exposure variables, and the tables or figures providing the evidence supporting the concluding statement. We also recorded details of how the statistical analysis was implemented and whether or not data were reported to be available. The data availability was determined separately for the primary outcome, the exposure, any potential confounders, and any effect modifiers, since it is commonly the case that the different variables have different sources.

The results of our survey are summarized in table 2. In total, we examined 90 articles, 69 of which were observational studies and had either a cross-sectional, case-control, or cohort design: We focus only on these 69 articles. For 84 percent of the articles, the data for the outcome and exposure came from original studies or from large ongoing studies. None of the articles reported that the outcome data were available to others, either from the authors or from a third party. In only one study were the exposure data available. However, in this study, "time" was the relevant exposure variable, with the study examining trends in cardiovascular risk factors through a series of surveys. It should be noted that we did not attempt to contact the authors and to request the analytical data and computer code used for their published analyses. Had the authors been contacted, it is not known how many would have been willing or able to provide the data and code.

Thirty percent of the articles did not report how the statistical analyses were implemented, while the remaining 70 percent reported using a specific software package. Neither the software for the statistical analysis nor the software for processing the measured data into analytical data was reported to be available. Of the articles where measured data required processing, 93 percent did not report how this processing was implemented.

METHODS FOR REPRODUCIBLE RESEARCH

Articles printed in journals are still the primary means by which scientific results are presented. However, reproducible research as defined in the previous section requires that arrangements be made for the distribution of analytical data and methods. While journals typically govern the distribution of the scientific findings, the task of distributing data and methods is relegated to the authors.

Today, the World Wide Web is the most convenient medium for distributing information to other researchers and is already playing a central role in the implementation of reproducible research. Many journals now have websites that can host supplementary materials for published articles, such as data that can be downloaded along with computer code for reproducing specific analyses. In addition, more detailed explanations of methods and complementary figures can be provided to the reader who intends to reproduce the published findings and to conduct competing analyses of the same data set.

LITERATE PROGRAMMING

The practice of posting data and code on either personal or journal websites is a significant first step. While making data and code available is certainly necessary, it is typically insufficient for others to reproduce results. An author must additionally provide details about how the code is linked to the data and which code sections are applied to which data.

A *compendium* is an article linked together with the data and code necessary for producing all of the results in the article (10, 11). The tools for constructing a compendium are modeled on the idea of *literate programming*, a phrase coined by Donald Knuth (12) and a concept extended by many others (13). A literate program combines a documentation

language with a programming language to produce an overall program that is self-documenting and more "literate." Knuth's original WEB system for writing literate programs combined the TEX documentation language with the Pascal programming language. In a literate program, one *weaves* the text and code to produce a human-readable document and *tangles* the code to produce a machine-executable file. The advantage of the literate programming approach is that the code and text can provide a running commentary on each other.

The specific details of how a compendium is created depend on the computing environment and programming languages used by the author. Gentleman and Temple Lang (10) propose using the R software environment (15) coupled with the LATEX document-formatting language. The general idea of a compendium is not tied to any one software package but, rather, the ideas of literate programming are easily applied to the documentation and programming language with which the researcher is familiar.

OPEN RESEARCH DATA LICENSES

It is understandable that authors do not make their research data available, if only because once data are released, there is little control over how the data will be used (16). A regime whereby partial rights to research data could be granted would allow some flexibility for authors to make data available without giving up complete control. For reproducible research to become the standard in epidemiology, limited access to data is a necessity.

We propose different classes of data licenses that provide partial rights to research data under prespecified conditions. In developing these classes, we borrow from standards created by the Creative Commons project (http://creativecommons.org), an organization devoted to creating licenses that provide partial rights to literary works. These ideas have also been discussed in the software community, where "open source" licenses are commonly used to provide partial rights to software products (e.g., the Open Source Initiative at http://opensource.org/).

The following list defines four possible classes of data licenses in order of increasing restrictiveness. We choose not to use precise legal definitions but rather outline the basic ideas.

1. *Full access*. The data can be used for any purpose.
2. *Attribution*. The data can be used for any purpose so long as the authors are cited (a specific citation should be provided).
3. *Share alike*. The data can be used to produce new findings or results. Any modifications to the data, including transformations, additions, or linkages to other data, which are used to produce the new findings, must be made available under the same terms.
4. *Reproduction*. The data can be used for the purpose of reproducing the results in the associated published article or for commenting on those results via a letter to the editor. No original findings based on the data may be published without explicit permission from the original investigators in a separate agreement.

Licenses providing partial rights to data can benefit both the donor and the recipient. The recipient obtains access to the data and an explicit understanding of the rights granted to him or her. The donor meets data disclosure obligations (from either granting agencies or journals) and is provided some measure of control over others' use of the data in an undesirable manner. In addition, the donor is relieved of having to negotiate potentially numerous requests for the data set. With the benefits also come the costs of such a licensing regime. The recipient must accept limitations to the data set by the donor, while the donor must initially invest time to arrange for data sharing and risks agreement violations by those using the data.

REPRODUCIBLE RESEARCH IN AIR POLLUTION AND HEALTH: A CASE STUDY

We demonstrate one implementation of reproducible research with a large observational study of the health effects of air pollution, the National Morbidity, Mortality, and Air Pollution Study (NMMAPS). NMMAPS is a national time-series study on the short-term health effects of air pollution, the goals of which are to 1) integrate multiple government databases that contain information on population health, ambient air pollution levels, weather variables, and socioeconomic variables for air pollution epidemiology; 2) develop statistical methods and computational tools for analyzing and interpreting the resulting database; and 3) estimate the short-term effects of air pollution on mortality and its uncertainty for the largest US metropolitan areas and for several geographic regions (17, 18).

Because of the regulatory context, quantification of air pollution risks is controversial. The assessments of risks are part of a highly charged policy debate and, consequently, statistical methods and data sources are subject to intense scrutiny by other scientists and interested parties. A recent review of the epidemiologic evidence on the health effects of fine particles described this debate (19), which will likely be revisited now that the Environmental Protection Agency (20) has promulgated its latest daily and annual standards for particulate matter. In the last few years, NMMAPS and several other large epidemiologic studies (21–23) have been a part of this policy debate (5).

As a first step toward developing higher standards of reproducibility, we created the Internet Health and Air Pollution Surveillance System for disseminating the entire NMMAPS database and the software for implementing all of our statistical analyses (http://www.ihapss.jhsph.edu/). Other scientists can fully reproduce our results, apply our methodology to their own data, or apply their methodology to the NMMAPS database. One of the goals of our approach is to raise the level of scientific debate by making all of our methods publicly available and to create new tools and standards that encourage others to do the same.

In addition to the Internet Health and Air Pollution Surveillance System website, we have created a compendium for a recent publication, "Seasonal Analyses of Air Pollution and Mortality in 100 US Cities" (24), which contains an analysis of the seasonal and regional variability of the health

TABLE 3. Making results from the National Morbidity, Mortality, and Air Pollution Study reproducible*

Research component	What we have done
Data	The entire NMMAPS† database is available to the public via the iHAPSS† website and the NMMAPS data package for R; the data are available under a "full access" class of license.
Methods	A full compendium written in $LaTeX$ and R is available for download.
Documentation	We have outlined our data-processing pipeline on the iHAPSS website, and papers/technical reports are available for download.
Distribution	We use the World Wide Web to disseminate our data and software.

* Details at http://www.biostat.jhsph.edu/~rpeng/reproducible/.
† NMMAPS, National Morbidity, Mortality, and Air Pollution Study; iHAPSS, Internet Health and Air Pollution Surveillance System.

effects of particulate matter. To allow others to reproduce our findings, we have developed a simple webpage that contains links to all of the data and computer code for generating the figures and tables in the article. The compendium is written with the literate programming techniques described in the previous section, an excerpt of which is shown in the Appendix. Readers can inspect the code for producing the results and for creating the tables/figures, as well as download the code and data to their own computers to run other analyses or produce different figures. A summary of our efforts can be found in table 3, and we have posted complete information about the data and methods used in this paper at http://www.biostat.jhsph.edu/~rpeng/reproducible/. In a recent study of fine particulate matter and hospitalizations among the elderly (25), we have applied the same principles of reproducibility and have posted information at http://www.biostat.jhsph.edu/MCAPS/.

DISCUSSION

In this article, we have proposed that reproducible research be the minimum standard in disseminating epidemiologic findings and have demonstrated the possibilities with a large ongoing study of air pollution and health. The policy implications of epidemiologic studies coupled with the investigation of smaller targets, the increasing use of complex databases, and the application of sophisticated statistical modeling can lead to research that is subject to intense scrutiny. The reproducibility of principal findings can foster rational discussions regarding the evidence in the data and serve as a bulwark against uninformed criticism.

The standard of reproducibility addresses some critical scientific issues, but its reach is still limited. In order to identify the issues that reproducibility can address, we must first agree on a model of the research process itself. One can think of an epidemiologic study as a sequence of stages, starting from the generation of the data by natural or other processes, to the collection of these data, to data processing and analysis, and then to the reporting of results. Prior to the generation of the data, one might also include the formulation of the hypotheses and the design of the study.

Reproducibility becomes meaningful in the stages of a study following the data collection. The processing of the data, as well as the analysis and subsequent presentation, can all be inspected if the research is reproducible. Beyond checking for statistical and programming errors, one can evaluate the sensitivity of the findings to certain modeling choices. By having the computer code used to process and analyze the data, others can obtain useful information regarding the many important choices made as part of the study.

Among the issues that cannot be addressed by reproducible research are those arising from stages of the research process prior to the data collection stage. Questions about the study design, the selection of subjects, the handling of nonrespondents, and many other facets of a study cannot be resolved with the analytical data alone. Similarly, it may not be possible to examine all relevant modeling choices, particularly those involving variables for which no data were originally collected. However, when we discuss these types of issues, we are moving closer to calling for full replication. If a particular study is fully replicable, then all aspects of the original study can be adjusted or modified. Clearly, full replication remains the ultimate standard by which we evaluate scientific evidence.

Data availability is the first and foremost challenge to reproducible epidemiologic research. Although this problem is not unique to epidemiology (26), being observational, evidence from epidemiologic studies is more often open to differing interpretations. It is exactly in such a circumstance that work needs to be open and reproducible. We have proposed a framework of "partial rights" to research data that would modulate the all-or-nothing scenario that exists today.

One impediment to making data available is preserving confidentiality. Health data are often obtained by making promises to individuals (either directly or through an intermediary) that confidential information about those individuals will not be released to the public. Under our definition, it would seem impossible to simultaneously honor those promises and make one's research reproducible. However, while the measured data often must be kept confidential, it may still be possible to provide summary statistics of the data upon which the analysis is based. For example, with time-series studies of air pollution and mortality, the individual mortality data are confidential, but the time series of aggregate counts for each county can be made available for large enough counties. Since the analysis is based entirely on those aggregate values, there is no need to release the individual-level data. This is a limited example, and although there is active discussion in the literature about disclosure limitation methods (27), the issue of releasing data for the purposes of reproducing scientific findings is in need of serious discussion.

The literature review served both to assess the state of reproducibility in the epidemiologic literature and to provide a "checklist" for producing a reproducible study. In addition to data availability, we identified a number of additional problems preventing epidemiologic findings from being reproduced. The sparse reporting of analytical methods

and the lack of computer code describing those methods are of concern. We have demonstrated how to use literate programming techniques to produce a reproducible document and the Web for distributing data and software. The reproducibility of the document is ensured by the use of tools that allow text and code to be intermingled to form a common source for the finished paper. In general, programming languages and statistical packages tend to change, and we do not presume that there is a single "best" environment. Rather, we describe the general concept of literate programming and highlight some specific tools that are available for encouraging such practice.

The call for reproducible research has already been echoed in other fields where computation and complex statistical methodology are critical for obtaining substantive results (7, 10, 11, 28–31). Biologists have made enormous progress toward integrating databases, sharing software, and making their analyses reproducible. Journals such as *Science* and *Nature* require deposition of biologic data into public repositories at the time of publication, and organizations such as the Microarray Gene Expression Data Society have developed rigorous standards for the reporting of microarray data (32). The Inter-University Consortium for Political and Social Research is a vast repository for social science data, providing archiving resources as well as standardization of data sets for a number of software environments. Social science investigators intent on making their research reproducible have a clear resource for sharing their data.

In addition to various field-specific efforts, the US National Institutes of Health now requires many of its grantees to implement a data-sharing policy for any research sponsored by the Institutes. Even more broadly, the federal government, via the Shelby Amendment of 1999 and the subsequent revision to the Office of Management and Budget Circular A110, requires data from any federally sponsored research to be made available upon request if the data were used in "developing an agency action that has the force and effect of law" (33, p. 220). It is not yet known what the full impact of either of these policies will be on the reproducibility of all biomedical research.

In the absence of full replication, reproducibility should become the minimum standard for epidemiologic research. In particular, studies with potential policy impact should be made reproducible to allow others to verify published findings and to conduct alternative analyses of the data. We have demonstrated through our case study that the standard of reproducibility can be achieved and have proposed a framework in which the results can be disseminated. The apparent unreliability of epidemiologic investigations predicted 10 years ago can be thwarted today by adopting new standards and embracing a more open research environment.

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REFERENCES

1. Samet JM. Epidemiology and policy: the pump handle meets the new millenium. Epidemiol Rev 2000;22:145–54.
2. Taubes G. Epidemiology faces its limits. Science 1995;269:164–9.
3. Bell ML, McDermott A, Zeger SL, et al. Ozone and short-term mortality in 95 US urban communities, 1987–2000. JAMA 2004;292:2372–8.
4. Kaiser J. Researchers and lawmakers clash over access to data. Science 1997;277:467. (DOI: 10.1126/science.277.5325.467).
5. Kaiser J. Evidence mounts that tiny particles can kill. Science 2000;289:22–3. (DOI: 10.1126/science.289.5476.22).
6. The PLoS Medicine Editors. Why bigger is not yet better: the problems with huge datasets. PLoS Med 2005;2:e55. (DOI: 10.1371/journal.pmed.0020055).
7. Schwab M, Karrenbach N, Claerbout J. Making scientific computations reproducible. Comput Sci Eng 2000;2:61–7. (http://sepwww.stanford.edu/research/redoc/).
8. Kaiser J. Software glitch threw off mortality estimates. Science 2002;296:1945–7. (DOI: 10.1126/science.296.5575.1945).
9. Colburn KA, Johnson PRS. Air pollution concerns not changed by S-PLUS flaw. Science 2003;299:665–6. (DOI: 10.1126/science.1082105).
10. Gentleman R, Temple Lang D. Statistical analyses and reproducible research. Berkeley, CA: Berkeley Electronic Press, 2004. (http://www.bepress.com/bioconductor/paper2).
11. Ruschhaupt M, Huber W, Poustka A, et al. A compendium to ensure computational reproducibility in high-dimensional classification tasks. Stat Appl Genet Mol Biol 2004;3:article 37. (http://www.bepress.com/sagmb/vol3/iss1/art37).
12. Knuth DE. Literate programming. Stanford, CA: Center for the Study of Language and Information, 1992.
13. Rossini A. Literate statistical practice. In: Hornik K, Leisch F, eds. Presented at the 2nd International Workshop on Distributed Statistical Computing, Vienna, Austria, March 15–17, 2001. (http://www.ci.tuwien.ac.at/Conferences/DSC-2001/Proceedings/Rossini.pdf).
14. Ihaka R, Gentleman R. R: a language for data analysis and graphics. J Comput Graph Stat 1996;5:299–314.
15. R Development Core Team. R: a language and environment for statistical computing. Vienna, Austria: R Foundation for Statistical Computing, 2005. (http://www.Rproject.org).
16. Rowen L, Wong GKS, Lane RP, et al. Intellectual property. Publication rights in the era of open data release policies. Science 2000;289:1881. (DOI: 10.1126/science.289.5486.1881).
17. Samet JM, Zeger SL, Dominici F, et al. The National Morbidity, Mortality, and Air Pollution Study, part I: methods and methodological issues. Cambridge, MA: Health Effects Institute, 2000.
18. Samet JM, Zeger SL, Dominici F, et al. The National Morbidity, Mortality, and Air Pollution Study, part II: morbidity and mortality from air pollution in the United States. Cambridge, MA: Health Effects Institute, 2000.

19. Kaiser J. Mounting evidence indicts fine-particle pollution. Science 2005;307:1858–61.
20. National ambient air quality standards for particulate matter. Research Triangle Park, NC: US Environmental Protection Agency Office of Air Quality Planning and Standards, 2005.
21. Dockery D, Pope CA, Xu X, et al. An association between air pollution and mortality in six U.S. cities. N Engl J Med 1993;329:1753–9.
22. Pope CA, Thun M, Namboodiri M, et al. Particulate air pollution as a predictor of mortality in a prospective study of U.S. adults. Am J Respir Crit Care Med 1995;151:669–74.
23. Pope CA, Burnett RT, Thun MJ, et al. Lung cancer, cardiopulmonary mortality, and long-term exposure to fine particulate air pollution. JAMA 2002;287:1132–41.
24. Peng RD, Dominici F, Pastor-Barriuso R, et al. Seasonal analyses of air pollution and mortality in 100 US cities. Am J Epidemiol 2005;161:585–94.
25. Dominici F, Peng RD, Bell ML, et al. Fine particulate air pollution and hospital admission for cardiovascular and respiratory diseases. JAMA 2006;295:1127–35.
26. Campbell EG, Clarridge BR, Gokhale M, et al. Data withholding in academic genetics: evidence from a national survey. JAMA 2002;287:473–80.
27. Fienberg SE. Conflicts between the needs for access to statistical information and demands for confidentiality. J Off Stat 1994;10:115–32.
28. Gentleman R. Reproducible research: a bioinformatics case study. Stat Appl Genet Mol Biol 2005;4:article 2. (http://www.bepress.com/sagmb/vol4/iss1/art2).
29. Johnson DH. Three objections to databases answered. In: APS observer. Vol 14. Washington, DC: Association for Psychological Science, 2001. (http://www.psychologicalscience.org/observer/1101/database.html).
30. Buckheit J, Donoho DL. Wavelab and reproducible research. In: Antoniadis A, ed. Wavelets and statistics. New York, NY: SpringerVerlag, 1995.
31. Gentleman RC, Carey VJ, Bates DM, et al. Bioconductor: open software development for computational biology and bioinformatics. Genome Biol 2004;5:R80. (DOI: 10.1186/gb-2004-5-10-r80).
32. Ball CA, Sherlock G, Parkinson H, et al. Standards for microarray data. (Letter). Science 2002;298:539. (DOI: 10.1126/science.298.5593.539b).
33. 45CFR74.36. Washington, DC: US Government Printing Office, 2003:220–1. (http://www.peo7.com/CFRFiles/PEOusCFR_45PUBLICWELFARE_119259.htm).

APPENDIX

Sweave Example

The following is taken from a vignette for reproducing the results reported in the paper by Peng et al. (24). The document is written in the LaTeX document-formatting language, and the portions between the <<>>= and @ symbols are written in the R language.

```
The national average estimates of the overall and seasonal short-term effects of \PMTen\
on mortality for lags 0, 1, and 2 are summarized in Table 2. These estimates were obtained by
pooling the city-specific maximum likelihood estimates from the main effect and pollutant-
season interaction models according to the hierarchical normal model.

<<nationalAverageEstimates,results=tex,echo=false>>=
Seasons <- c("Winter", "Spring", "Summer", "Fall", "All Seasons")
Lags <- paste("Lag", 0:2); exclude <- c("hono", "anch")

## Load non-seasonal estimates
load(file.path("results", "city-specific-est.pm10.rda"))
results <- lapply(results, function(x) x[setdiff(names(x), exclude)])

## Pool estimates
betacovTotal <- lapply(results, extractBetaCov, pollutant = poll)
pooledTotal <- lapply(betacovTotal, poolCoef)

## Load seasonal estimates
load(file.path("results", "seasonal.factor2.lag.012.pm10.rda"))
results <- lapply(results, function(x) x[setdiff(names(x), exclude)])

## Pool estimates by season
pooledSeas <- lapply(results, coefSeasonal, pollutant=poll,
method=method)
pooled <- lapply(seq(along = pooledSeas), function(i) {
    m <- rbind(pooledSeas[[i]], pooledTotal[[i]])
    rownames(m) <- Seasons
    m
})
@
```

focus

Deming, data and observational studies

A process out of control and needing fixing

"Any claim coming from an observational study is most likely to be wrong." Startling, but true. Coffee causes pancreatic cancer. Type A personality causes heart attacks. Trans-fat is a killer. Women who eat breakfast cereal give birth to more boys. All these claims come from observational studies; yet when the studies are carefully examined, the claimed links appear to be incorrect. What is going wrong? Some have suggested that the scientific method is failing, that nature itself is playing tricks on us. But it is our way of studying nature that is broken and that urgently needs mending, say **S. Stanley Young** and **Alan Karr**; and they propose a strategy to fix it.

Science works by experiments that can be repeated; when they are repeated, they must give the same answer. If an experiment does not replicate, something has gone wrong. In a large branch of science the experiments are observational studies: we look at people who eat certain foods, or take certain drugs, or live certain lifestyles, and we seem to find that they suffer more from certain diseases or are cured of those diseases, or – as with women who eat more breakfast cereal – that more of their children are boys. The more startling the claim, the better. These results are published in peer-reviewed journals, and frequently make news headlines as well. They seem solid. They are based on observation, on scientific method, and on statistics. But something is going wrong. There is now enough evidence to say what many have long thought: that any claim coming from an observational study is most likely to be wrong – wrong in the sense that it will not replicate if tested rigorously.

As long ago as 1988[1,2] it was noted that there were contradicted results for case–control studies in 56 different topic areas, of which

Table 1. We have found 12 papers in which claims coming from observational studies were tested in randomised clinical trials. Many of the trials are quite large. In most of the observational studies multiple claims were tested, often in factorial designs, e.g. vitamin D and calcium individually and together along with a placebo group. Note that none of the claims replicated in the direction claimed in the observational studies and that there was statistical significance in the opposite direction five times

ID no.	*Pos.*	*Neg.*	*No. of claims*	*Treatment(s)*	*Reference*
1	0	1	3	Vit E, beta-carotene	*NEJM* 1994; **330**: 1029–1035
2	0	3	4	Hormone Replacement Ther.	*JAMA* 2003; **289**: 2651–2662, 2663–2672, 2673–2684
3	0	1	2	Vit E, beta-carotene	*JNCI* 2005; **97**: 481–488
4	0	0	3	Vit E	*JAMA* 2005; **293**: 1338–1347
5	0	0	3	Low Fat	*JAMA*. 2006; **295**: 655–666
6	0	0	3	Vit D, Calcium	*NEJM* 2006; **354**: 669–683
7	0	0	2	Folic acid, Vit B6, B12	*NEJM* 2006; **354**: 2764–2772
8	0	0	2	Low Fat	*JAMA* 2007; **298**: 289–298
9	0	0	12	Vit C, Vit E, beta-carotene	*Arch Intern Med* 2007; **167**: 1610–1618
10	0	0	12	Vit C, Vit E	*JAMA* 2008; **300**: 2123–2133
11	0	0	3	Vit E, Selenium	*JAMA* 2009; **301**: 39–51
12	0	0	3	HRT + Vitamins	*JAMA* 2002; **288**: 2431–2440
Totals	0	5	52		

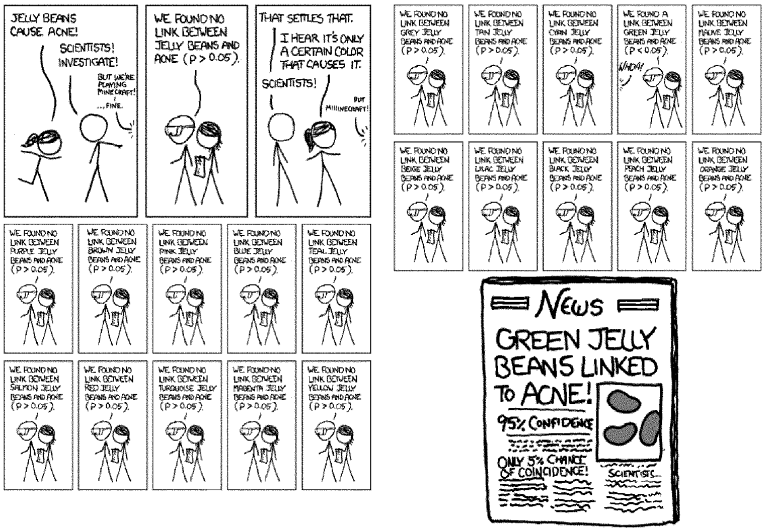


Figure 1. There is no overall effect of jelly beans on acne. Bummer. How about subgroups? Often subgroups are explored without alerting the reader to the number of questions at issue. Courtesy xkcd, http://xkcd.com/882/

cancer and things that cause it or cure it were by far the most frequent. An average of 2.4 studies supported each association – and an average of 2.3 studies did not support it. For example, three studies supported an association between the anti-depressant drug reserpine and breast cancer, and eight did not. It was asserted[2] that "much of the disagreement may occur because a set of rigorous scientific principles has not yet been accepted to guide the design or interpretation of case-control research". Problems extend to essentially all observational studies. Little progress has been made to adopt rigorous scientific principles. Some journal article titles give a flavour of the sentiments: "Epidemiology faces its limits", "Is it time to call it a day?", "Have we learned from our mistakes, or are we doomed to compound them?". In the popular press, an article by Jonah Lehrer in the *New Yorker*[3] bore the subheading "Is there something wrong with the scientific method?" and seemed to imply that replicability was no longer occurring; it concluded with the phrase: "When the experiments are done, we still have to choose what to believe." No. In the Lehrer example the motivating finding was wrong and therefore should not be expected to replicate.

It may not be appreciated how often observational claims fail to replicate. In a small sample in 2005[4], of 49 claims coming from highly cited studies, 14 either failed to replicate entirely or the magnitude of the claimed effect was greatly reduced (a regression to the mean). Six of these 49 studies were observational studies, and in these six, in effect, randomly chosen observational studies, five failed to replicate. This last is an 83% failure rate. In an ideal world in which well-studied questions are addressed and statistical issues are accounted for properly, few statistically significant claims are false positives. Reality for observational studies is quite different.

We ourselves carried out an informal but comprehensive accounting of 12 randomised clinical trials that tested observational claims – see Table 1. The 12 clinical trials tested 52 observational claims. They all confirmed no claims in the direction of the observational claims. We repeat that figure: 0 out of 52. To put it another way, 100% of the observational claims failed to replicate. In fact, five claims (9.6%) are statistically significant in the clinical trials *in the opposite direction* to the observational claim. To us, a false discovery rate of over 80% is potent evidence that the observational study process is not in control. The problem, which has been recognised at least since 1988, is systemic.

The cause of it all

The cause is elusive and can be considered both technically and operationally. Individual researchers, the workers, respond rationally to incentives by publishing papers in peer-reviewed journals and securing funding for their research. The quality of their papers is judged by funding agencies and journal editors, the important managers of the observational study production system. We can turn here to statistician W.

Box 1. Amplification of W. Edwards Deming's thinking

It is worth contrasting control of an observational study with that of a production process. When Deming first looked at manufacturing, it was common to inspect only the final product, be it a screw or a car, to maintain product quality. There was little or no systematic feedback from problems with the final product to places in the process where those defects occurred. This inspection of the final product works, but it is frightfully expensive. Deming's insight was to control each step of the process where errors occur so that the final frequency of bad product is greatly reduced. Now, world-wide, industrial production is process control. Control the steps of the process and the final product will largely take care of itself. Consider the production of an observational study. Workers – that is, researchers – do data collection, data cleaning, statistical analysis, interpretation, writing a report/paper. It is a craft with essentially no managerial control at each step of the process. In contrast, management dictates control at multiple steps in the manufacture of computer chips, to name only one process control example. But journal editors and referees inspect only the final product of the observational study production process and they release a lot of bad product. The consumer is left to sort it all out. No amount of educating the consumer will fix the process. No amount of teaching – or of blaming – the worker will materially change the group behaviour. Deming's insight was to admonish management to redesign an out-of-control process.

Edwards Deming[5], the most visionary innovator ever on quality control and the man who transformed first Japanese car manufacturing then manufacturing quality control worldwide (see Box 1). Deming said: "The worker is not the problem. The problem is at the top! Management!" To Deming, blaming the workers – individual researchers – is as incorrect as it is useless. Bringing the system under control is the responsibility of those managing it.

What is needed to fix the system? Among Deming's famous "Fourteen Points for Management", the third is most directly relevant: *cease dependence on inspection to achieve quality*. Every successful company today relies on control of the process; they do not wait until the end of the process and then throw away bad product. That would be product control, not process control. It is wasteful to make something, then inspect and throw away the bad product. Instead, every step of the process is monitored and controlled, so that bad product is not made. The "observational studies industry" must build a good product; journal editors cannot inspect bad product out at the publication stage, let alone the replication stage. If the processes are controlled by management, the products can be sound studies. Control of the processes is feasible, and requires attention to the incentives, publications and grants. First we examine three of the main technical difficulties with observational studies: Multiple testing, bias, and multiple modelling.

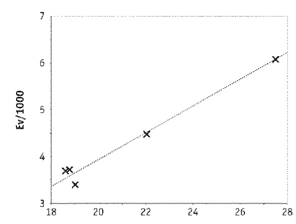
Multiple testing

False positives do occur, even in an ideal world. When many questions are asked of the same data, some of those questions will by chance come up positive. Producing at least one false positive becomes a near certainty unless the data analysis accounts for the multiple questions. Figure 1, from the excellent website xkcd.com, brilliantly explains the basic problem. The "females eating cereal leads to more boy babies" claim translated the cartoon example into real life. The claim appeared in the *Proceedings of the Royal Society, Series B*. It makes essentially no biological sense, as for humans the Y chromosome controls gender and comes from the male parent. The data set consisted of the gender of children of 740 mothers along with the results of a food questionnaire, not of breakfast cereal alone but of 133 different food items – compared to only 20 colours of jelly beans. Breakfast cereal during the second time period at issue was one of the few foods of the 133 to give a positive. We reanalysed the data[6], with 262 t-tests, and concluded that the result was easily explained as pure chance.

For those who want more than cartoons, a simple web simulation[7] is convincing that multiple testing needs to be controlled. Although many workers who are thought leaders of researchers doing observational studies argue against any correction of the analysis for multiple testing[8], managers can require that authors deal with multiple testing.

Bias

Whereas multiple testing is random error, bias is systematic error. To illustrate it, consider channelling, where doctors steer certain patients to particular treatments. For example, doctors directed HIV patients at high cardiovascular risk to a particular HIV treatment, abacavir, and lower-risk patients to other drugs, preventing a simple assessment of abacavir compared to other treatments. An analysis that did not correct for this bias unfairly penalised the abacavir, since its patients were more high-risk so more of them had heart attacks (Figure 2). Another problem is that covariate adjustment is widely used, but is vulnerable to manipulation and is well known to give unreliable results when the treatment groups are not comparable; see "Multiple modelling" below. Missing factors, unmeasured confounders, and loss to follow-up can also lead to bias. For example, in a study published in *Pediatrics*[9], offspring IQ was the issue, yet IQ of the fathers was not measured and of the 505 children starting the study, 256 (50.7%) were lost to follow-up. By selecting papers with a significant p-value, negative studies are selected against – which is publication bias (see Box 2).



	Drug	*% high-risk patients*	*MI events per 1000 patient years*
1	zidovudine	19.0	3.43
2	stavudine	18.8	3.72
3	lamivudine	18.6	3.68
4	didanosine	22.1	4.47
5	abacavir	27.5	6.13

Figure 2. Events per thousand patient-years are plotted against estimated risk of a heart attack. Risky patients were channelled to the HIV drug ABC, abacavir, and those patients had more heart attacks, as shown by the uppermost point on the graph. Risk-adjusted, all the drugs appear to be of equal risk. Source: *Lancet* **371**, 1417 ff.

Box 2. Publication bias

There is general recognition that a paper has a much better chance of acceptance if something new is found. This means that, for publication, the data in the paper has to be found on a p-value less than 0.05. From Deming's point of view, this is quality by inspection. The journals are placing reliance on a statistical test rather than examination of the methods and steps that lead to a conclusion. So to having a p-value less than 0.05, some might be tempted to game the system[9] through multiple testing, multiple modelling or other treatments of data in some neighbourhood of the final test leads to a small p-value. Researchers can be quite creative in devising a plausible story to fit the statistical finding.

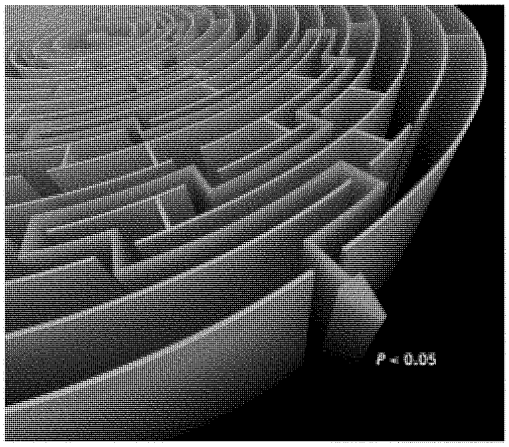


Figure 3. The path through a complex process can appear quite simple once the path is defined. Which terms are included in a multiple linear regression model? Each turn in a maze is analogous to including or not a specific term in the evolving linear model. By keeping an eye on the p-value on the term selected to be at issue, one can work towards a suitably small p-value. © ktsdesign - Fotolia

Multiple modelling

This problem is akin to – but less well recognised and more poorly understood than – multiple testing. For example, consider the use of linear regression to adjust the risk levels of two treatments to the same background level of risk. There can be many covariates, and each set of covariates can be in or out of the model. With ten covariates, there are over 1000 possible models. Consider a maze as a metaphor for modelling (Figure 3). The red line traces the correct path out of the maze. The path through the maze looks simple, once it is known. Returning to a linear regression model, terms can be put into and taken out of a regression model. Once you get a *p*-value smaller than 0.05, the model can be frozen and the model selection justified after the fact. It is easy to justify each turn.

The combination of multiple testing and multiple modelling can lead to a very large search space, as the example of bisphenol A in Box 3 shows. Such large search spaces can give small, false positive *p*-values somewhere within them. Unfortunately, authors and consumers are often like a deer caught in the headlights and take a small *p*-value as indicating a real effect.

How can it be fixed? A new, combined strategy

It should be clear by now that more than small-scale remedies are needed. The entire system of observational studies and the claims that are made from them is no longer functional, nor is it fit for purpose. What can be done to fix this broken system? There are no principled ways in the literature for dealing with model selection, so we propose a new, composite strategy. Following Deming, it is based not upon the workers – the researchers – but on the production system managers – the funding agencies and the editors of the journals where the claims are reported.

We propose a multi-step strategy to help bring observational studies under control (see Table 2). The main technical idea is to split the data into two data sets, a modelling data set and a holdout data set. The main operational idea is to require the journal to accept or reject the paper based on an analysis of the modelling data set without knowing the results of applying the methods used for the modelling set on the holdout set *and* to publish an addendum to the paper giving the results of the analysis of the holdout set. We now cover the steps, one by one.

1 The data collection and clean-up should be done by a group separate from the analysis group. There can be a temptation on the part of the analyst to do some exploratory data analysis during the data clean up. Exploratory analysis could lead to model selection bias.

2 The data cleaning team creates a modelling data set and a holdout set and gives the modelling data set, less the item to be predicted, to the analyst for examination.

Table 2. Steps 0–7 can be used to help bring the observational study process into control. Currently researchers analysing observational data sets are under no effective oversight

Step	*Process / Action*
0	Data are made publicly available
1	Data cleaning and analysis separate
2	Split sample: A, modelling; and B, holdout (testing)
3	Analysis plan is written, based on modelling data only
4	Written protocol, based on viewing predictor variables of A
5	Analysis of A only data set
6	Journal accepts paper based on A only
7	Analysis of B data set gives Addendum

3 The statistical analysis plan is written based on access to all the modelling data except the response(s) to be predicted[12].
4 The analyst writes down and files the statistical protocol. The point is that the analysis should not be guided by looking at the results of exploratory analysis. It is too easy to move predictors into and out of an evolving statistical models. Reconsider the maze (Figure 3). Given flexibility, the analyst can move the answer around. Such flexibility must be prevented.
5 The analysis is done and the paper written (see Box 2).
6 The journal agrees to accept or reject the paper without knowing the results of the analysis of the holdout data set.
7 Once that analysis is done, an addendum will be added to the paper using the specified analysis on the holdout set.

A hold-out set of data can be tested against claims; if the test fails, both author and journal stand to be embarrassed

The holdout set is the key. Both the author and the journal know there is a sword of Damocles over their heads. Both stand to be embarrassed if the holdout set does not support the original claims of the author. Both the author and the journal are at present living in a largely risk-free environment. False results may never be overturned. The claim that "Type A personality causes heart attacks" still lives and took decades to be declared invalid. Most who took the claim at face value to be true never got the word that it is not true. The myth still lives. The protocol we suggest would have scotched it at birth.

Before our steps 1–7 begin, there is another step to be made. Step 0, making data available, provides additional oversight. Note that the split-sample strategy can control multiple testing and multiple modelling, but not bias. Bias can be controlled by setting a threshold of effect, say for risk ratio a value of 3 to 4[13], of effect to be considered actionable evidence of cause and effect.

Box 3. Bisphenol A

The US Center for Disease Control assayed the urine of around 1000 people for 275 chemicals, one of which was bisphenol A (BPA). One resulting claim was that BPA is associated with cardiovascular diagnoses, diabetes, and abnormal liver enzyme concentrations. BPA is a chemical much in the news and under attack from people fearful of chemicals. The people who had their urine assayed for chemicals also gave a self-reported health status for 32 medical outcomes. For each person, ten demographic variables (such as ethnicity, education, and income) were also collected. There are 275 × 32 = 8800 potential endpoints for analysis. Using simple linear regression for covariate adjustment, there are approximately 1000 potential models, including or not including each demographic variable. Altogether the search space is about 9 million models and endpoints. The authors remain convinced that their claim is valid.

Deer in Headlights. A deer caught in the headlights will freeze, much like an author or reader seeing a p-value < 0.05, and think there must be a real effect. Authors can exploit this phenomenon intentionally or fool both themselves and the reader. Illustration: Tom Boulton

What can be done?

Note that workers have known of problems since at least 1988 and have instituted none of the steps 0–7 in Table 2. Asking authors voluntarily to provide protocol, data and analysis code has been very largely ineffective. There is a real limit to what an individual can do to improve the situation, as most of us are consumers. Individuals can write letters to the editor saying that without access to data the research is largely "trust me" science. The incentives need to be changed and that can only come from the managers of the process. Managers cannot carefully examine each published claim, but funding agencies and editors can require "reproducible research". Reproducible research is research where the study protocol, the electronic data set used for the paper, and the analysis code are all publicly available. Managers can also require split-sample analysis strategies and other methods to protect against false positives. At present, researchers – and, just as important, the public at large - are being deceived, and are being deceived in the name of science. This should not be allowed to continue.

References

1. Mayes, L. C., Horwitz, R. I. and Feinstein, A. R. (1988) A collection of 56 topics with contradictory results in case-control research. *International Journal of Epidemiology*, **17**, 680–685.
2. Feinstein, A. R. (1988) Scientific standards in epidemiologic studies of the menace of daily life. *Science*, **242**, 1257–1263.
3. Lehrer, J. (2010) The truth wears off. *New Yorker*, December 13th, p. 52.
4. Ioannidis, J. P. A. (2005) Contradicted and initially stronger effects in highly cited clinical research. *Journal of the American Medical Association*, **294**, 218–228.
5. Wikipedia (2011) W. Edwards Deming. http://en.wikipedia.org/wiki/W._Edwards_Deming
6. Young, S. S., Bang, H. and Oktay, K. (2009) Cereal-induced gender selection? Most likely a multiple testing false positive. *Proceedings of the Royal Society, Series B*, **654**, 1211–1212.
7. Dallal, J. (2011) There must be something buried in here somewhere. http://www.jerrydallal.com/LHSP/multtest.htm
8. Rothman, K. J. (1990) No adjustments are needed for multiple comparisons. *Epidemiology*, **1**, 43–46.
9. Perera, F. P., Li, Z., Whyatt, R., Hoepner, L., Wang, S., Camann, D. and Rauh, V. (2009) Prenatal airborne polycyclic aromatic hydrocarbon exposure and child IQ at age 5 years. *Pediatrics*, **124**, e195–e202
10. Glaeser, E. L. (2006) Researcher incentives and empirical methods. Harvard Institute of Economic Research Discussion Paper No. 2122. http://ssrn.com/abstract=934557
11. Young, S. S. and Yu, M. (2009) To the Editor. *Journal of the American Medical Association*, **301**, 720–721.
12. Rubin, D. B. (2007) The design *versus* the analysis of observational studies for causal effects: Parallels with the design of randomized trials. *Statistics in Medicine*, **26**, 20–36.
13. Temple, R. (1999) Meta-analysis and epidemiologic studies in drug development and postmarketing surveillance. *Journal of the American Medical Association*, **281**, 841–844.

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