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AGENCY USE OF SCIENCE IN THE RULEMAKING PROCESS: PROPOSALS FOR IMPROVING TRANSPARENCY AND ACCOUNTABILITY

HEARING

BEFORE THE

SUBCOMMITTEE ON
REGULATORY AFFAIRS AND FEDERAL
MANAGEMENT

OF THE

COMMITTEE ON
HOMELAND SECURITY AND
GOVERNMENTAL AFFAIRS
UNITED STATES SENATE

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AGENCY USE OF SCIENCE IN THE RULEMAKING PROCESS: PROPOSALS FOR IMPROVING TRANSPARENCY AND ACCOUNTABILITY

THURSDAY, MARCH 9, 2017

U.S. SENATE,
SUBCOMMITTEE ON REGULATORY,
AFFAIRS AND FEDERAL MANAGEMENT,
OF THE COMMITTEE ON HOMELAND SECURITY
AND GOVERNMENTAL AFFAIRS,
Washington, DC.

The Committee met, pursuant to notice, at 10:15 a.m., in room 342, Dirksen Senate Office Building, Hon. James Lankford, Chairman of the Subcommittee, presiding.

Present: Senators Lankford, Daines, Heitkamp, Carper, Hassan, and Harris.

OPENING STATEMENT OF SENATOR LANKFORD[1]

Senator LANKFORD. Good morning. Welcome to today's Subcommittee hearing entitled Agency Use of Science in the Rulemaking Process: Proposals for Improving Transparency and Accountability.

Over 2 years ago, this Subcommittee began an in-depth review of the rulemaking process, tackling subjects such as retrospective review, agency use of guidance, and issues surrounding small business' concerns when it comes to improving the regulatory outcomes. This morning we will continue our regulatory work by examining how agencies use scientific information to inform their regulatory decision making.

American people should be confident that when agencies regulate they are relying on up-to-date, accurate, and unbiased information. To put it simply, agencies should rely on the best available information and make decisions based on the weight of that information.

When determining whether scientific information is the best available, agencies should consider things like whether information has been peer-reviewed by an independent third party, whether the conclusions are verifiable and reproducible, whether the information's use is consistent with its intended purpose, and whether the data is transparent and publicly available.

[1] The prepared statement of Senator Lankford appears in the Appendix on page 35.

This is not a new idea. Presidents from both parties have stressed the importance of relying on sound science to inform regulatory decisions. Executive Order (EO) 12866, which has been in place since 1993, and endorsed by every President since, directs agencies to base decisions on the best reasonably obtainable, scientific and technical information. Eight years ago, President Obama went even further by issuing a memorandum to agency heads guaranteeing scientific integrity by following a list of principles that included consideration of well-established scientific processes and urging transparency to the public. And in 2011, President Obama issued Executive Order 13563, where he directed each agency to ensure the objectivity of any scientific and technical information used to support regulatory actions.

Yet, despite these clear directives, agencies continue to use questionable science to support their regulatory decisions, or we do not know the background on science. For example, in 2015, when the Environmental Protection Agency (EPA) proposed a ban on chlorpyrifos, an insecticide that farmers have been using successfully for decades, the agency based the regulation on a study that was discredited by their own scientific advisory panel and by the U.S. Department of Agriculture (USDA).

I understand agencies often face difficult choices and not all studies come to the same conclusion, but it is very concerning when agencies are not open about why they chose to use a study with such significant criticism. When agencies hide information from both Congress and the American people, it is our job to question motives and methods as a part of oversight.

Transparency is not an unreasonable request. In fact, it will go a long way in enforcing better regulations and heading off lawsuits in the future. When agencies issue regulations that place legally binding requirements on the American people, the data and methods or models the agency used should be publicly available for independent, third-party review.

When many of the most costly Clean Air Act (CAA) regulations are based on a single Harvard study from 1993, EPA should not be able to hide behind the excuse they can't release the study because they do not own it, Harvard does, despite the fact that Harvard receives well over half a billion dollars in Federal awards.

Examples like these call into question whether agencies are using best information because it is unknown, not because there is just a false accusation. We just don't know, and the American people do deserve to be able to know when these things impact their lives in such a significant way.

Each administration has their own priorities, but the principles supporting regulatory decisions should remain constant, regardless of who occupies the White House. If past administrations' attempts to encourage agencies to base their regulatory decisions on transparent, sound science have failed, Congress should consider establishing new legal requirements.

I look forward to discussing steps Congress can take to implement basic, fundamental requirements that have been endorsed by both Democrat and Republican administrations for decades.

Senator Heitkamp is running a little bit behind, though I will always tease her and say the lady is never late, but I will recognize

her for an opening statement if she chooses to give that orally, or to be able to put that into the permanent record if she does not choose to.

With that I would like to recognize our witnesses. Let me introduce them all and then we will do a swearing-in, and then we will take your testimony.

The Hon. Susan Dudley is the Director of the Regulatory Studies Center and Distinguished Professor of Practice in the Trachtenberg School of Public Policy and Public Administration, George Washington (GW) University. Before joining the faculty at GW, she served as the Administrator of the Office of Information and Regulatory Affairs (OIRA), from 2007 to 2009. Thanks for being here.

Dr. Andrew Rosenberg is the Director of the Center for Science and Democracy at the Union of Concerned Scientists. Before joining the Union of Concerned Scientists, he served as the Northeast Regional Administrator of the National Marine Fisheries Service (NMFS) at the National Oceanic and Atmospheric Administration (NOAA). Thanks again.

Dr. Nancy Beck is a senior director of Regulatory and Science Policy at the American Chemistry Council (ACC). Prior to joining the ACC she served as a toxicologist and science policy analyst at the Office of Management and Budget (OMB's) Office of Information and Regulatory Affairs from 2002 to 2012.

I do thank all of the witnesses for appearing.

It is our custom, as a Subcommittee and as a committee, to swear in all witnesses, so if you would all please rise and raise your right hand.

Do you swear the testimony you will give before this committee will be the truth, the whole truth, and nothing but the truth, so help you, God?

Ms. DUDLEY. I do.

Mr. ROSENBERG. I do.

Ms. BECK. I do.

Senator LANKFORD. Thank you. You may be seated. Let the record reflect the witnesses have all answered in the affirmative.

We do use a timing system here. That would be a 5-minute time clock that will start in front of you, countdown for your opening statements. Obviously all of your written statements will go into the permanent record already, and so we are welcome to be able to receive your oral testimony.

Susan Dudley, you are up first.

TESTIMONY OF SUSAN DUDLEY,[1] DIRECTOR, REGULATORY STUDIES CENTER, THE GEORGE WASHINGTON UNIVERSITY

Ms. DUDLEY. Thank you very much, Chairman Lankford, and it is good to meet you, Senator Hassan.

Effective regulatory policy that focuses resources on addressing real threats to public health and the environment depends on reliable scientific information and transparent policy choices, so your hearing is important.

I do not think anyone wants science to be politicized, but no one is immune to the temptation to put a spin on science to advance

[1] The prepared statement of Ms. Dudley appears in the Appendix on page 38.

a policy goal. Politicization can arise when political decisionmakers attempt to distort scientific findings, but also when scientists and others attempt to exert influence on policy decisions by how they present scientific information.

My prepared testimony focuses on the second type of politicization. It identifies two problems that current regulatory institutions tend to aggravate. The first is when scientists, intentionally or not, insert but do not disclose their own policy preferences in the scientific advice they provide decisionmakers. I have called this "hidden policy judgments" and others have called it "advocacy science" or "normative science." The second problem is the tendency to camouflage controversial policy decisions as science. For this I adopt Wendy Wagner's colorful term, a "science charade."

Institutional arrangements tend to aggravate both the hidden policy judgments and science charades, which threaten the credibility of science and harm regulatory policy. Many of those involved in regulatory decisions have incentives to hide policy preferences, such as how to deal with uncertainty inherent in assessments of risk, and to dismiss, and even denigrate dissenting views. Key policy choices, disguised as science, too often rest with technical staff, while policymakers are able to avoid responsibility by claiming that their hands were tied by the science.

In thinking about reforms to improve how science is used in regulation, clarifying which aspects of the decision are matters of science and which are matters of policy is essential to avoid both hidden policy judgments and the science charade. This was a key finding of a 2009 Bipartisan Policy Center (BPC) report, as well as a 1983 National Research Council (NRC) book.

In a forthcoming paper, Marcus Peacock and I offer 10 recommendations. I boiled those down to eight in my written testimony, and will trim them down to five for the remaining few minutes that I have.

First, we must recognize that science is a positive discipline that can inform, but not decide, appropriate policy. In drafting authorizing legislation, Congress should not delegate decisions to agencies on the pretense that science alone can make the normative decision of what policy ought to be.

Second, science advisory panels can provide a necessary and valuable source of information and peer review for agencies, but greater efforts should be made to restrict their advice to matters of science and not ask them to recommend policy. Further, a 2012 Keystone Center report emphasized all potential panelists on those science advisory boards will have conscious and unconscious biases, so it is important to select panelists with diverse perspectives and expertise, who are willing to engage in open discussion and are open to considering other views.

Third, risk assessments necessarily involve assumptions and judgments as well as pure scientific inputs, yet they often generate precise-sounding predictions that hide not only considerable uncertainty about actual risk but hidden judgments. Greater transparency regarding the assumptions and policy rationales for choosing one set of assumption or models over another would encourage more openness and constructive discussion about science and policy.

Fourth, reproducibility is important and it requires sharing of underlying data. I understand and appreciate concerns about disclosure of personally identifiable information (PII) and confidential information, but many Federal agencies have successful guidelines allowing access to data containing PII, using tiered approaches commensurate with the sensitivity of the information.

And finally, the scientific method depends on falsifiable hypotheses, data gathering, replication, dissent, and challenge—Reforms that intentionally engage rather than avoid competing views and that subject scientific predictions to ex-post evaluation would go a long way toward improving underlying science and the decisions that depend on it.

Legislation both Senators Lankford and Heitkamp have introduced, could be constructive. One bill that you introduced just yesterday would require advanced notices of proposed rulemaking for high-impact regulations, and one that you introduced together last session, would have required agencies to plan for ex-post review when proposing new rules, and that provides that feedback.

So I will close there, and thank you again for inviting me.

Senator LANKFORD. Thank you. Dr. Rosenberg.

TESTIMONY OF ANDREW A. ROSENBERG, PH.D.,[1] DIRECTOR, CENTER FOR SCIENCE AND DEMOCRACY, UNION OF CONCERNED SCIENTISTS

Mr. ROSENBERG. Chairman Lankford, Senator Hassan, Members of the Subcommittee, and Ranking Member Heitkamp, thank you for the opportunity to testify today on the important role of science and rulemaking process.

I am Andrew Rosenberg, Director of the Center for Science and Democracy at the Union of Concerned Scientists, and I have more than 25 years of experience as a scientist in government service, academia, and the private sector. I have served as a scientist and regulator in Democratic and Republican administrations, including as Deputy Director of NOAA Fisheries, as you noted. And in academia, I was the Dean of Life Sciences and Agriculture at the University of New Hampshire.

Independent science plays a critical role in the policy decisions made by the Federal Government that impact Americans' health and safety, and the science process consists of continuous and incremental discoveries in multiple fields of study, accumulating a weight of evidence and building toward broad acceptance of facts within the scientific community.

Weight of evidence refers to the cumulative body of scientific research and analysis that pertains to a particular subject. Weight refers not only to the number of studies but also their importance, robustness, and credibility in drawing scientific inference. Credibility relates to the design of the study, analytical methods, methods of inference, as well as provenance of the work with regard to potential conflicts of interest, peer reviews conducted, and comparisons with other relevant studies.

A valid and credible scientific process consists of a rigorous examination of ideas, review and critique by technically qualified

[1] The prepared statement of Mr. Rosenberg appears in the Appendix on page 49.

peers, open exchange of ideas among colleagues, and protection against manipulation of results by vested interests.

I serve as a regular reviewer for scientific journals, as a member of editorial boards, and as an independent reviewer for national and international reports. In this capacity, I consider the framing of the study, the methods, the results, the researchers' interpretation in light of my knowledge of the field, and relevant scientific literature. I may not agree with the conclusions drawn by the researchers, but if the aforementioned components are well-executed then the study contributes to the body of evidence, in my view.

Every study is subtly different and should be judged by experts in the field on its merits, and in my view, best available science is research that is conducted in accordance with well-established scientific practices, including well-designed investigation, logical statistically rigorous analyses, clear documentation of data collection and analytical methods, careful peer review of results free from external influences seeking a particular policy outcome.

I strongly believe that this process cannot be legislated without undermining innovation and unduly constraining the scientific information available to policymakers and to the public. If one were to legislate what should legally be considered best available science, it would prevent the innovation and flexibility that is inherent in the scientific process. This ability to innovate is essential for agencies as they address new discoveries, such as emerging public health threats.

Public access to science that underlies regulatory decisions is important as part of our democracy and to ensure the rationale for decisions is clear, even if all do not agree with the final policy outcomes. On this point it is important to distinguish between data and science. The scientific information critical for an informed public concerns how studies are conducted, how information is interpreted, and inferences are drawn. This is not dissimilar from the information a peer reviewer like me considers in evaluating a study, albeit for the public in a non-technical form. Peer reviewers, in general, do not review raw data.

Agency rulemaking must be informed by independent science advice that is free from political pressure. Twenty-four Federal agencies have developed scientific integrity policies that help ensure the independence of scientific advice. There is now legislation in both House and Senate that would codify scientific integrity policies into law, which I view as a positive step for protecting science-informed policymaking. Strengthening peer review policies in several agencies further safeguards government science.

Best available science should be used to describe the weight of scientific evidence developed by a credible process for ensuring independence from political influence. Agency scientists supported by a commitment to independent science, scientific integrity policies, and appropriate transparency measures should be trusted to provide science advice to decisionmakers, and I agree it is advice. All Americans benefit when science is used to inform policy, and its integrity in the rulemaking process is imperative for a functional democracy and a safer, cleaner planet for all.

Thank you Mr. Chairman, Ranking Member, and Members of the Committee. I appreciate the opportunity.

Senator LANKFORD. Dr. Beck.

TESTIMONY OF NANCY BECK, PH.D.,[1] SENIOR DIRECTOR, REGULATORY SCIENCE POLICY, AMERICAN CHEMISTRY COUNCIL.

Ms. BECK. Good morning, Chairman Lankford, Ranking Member Heitkamp, Senator Hassan, and Senator Harris. I am honored to be here today representing the American Chemistry Council. My name is Nancy Beck and I have spent over 15 years working at the intersection of science and policy.

The business of chemistry is a critical component for manufacturing safe, high-quality products. ACC member companies and the public rely on science to innovate, to advance product stewardship, and to prove the assessments of chemical risk. ACC members expect high-quality science and objective assessment processes to underpin regulatory decisions.

Reliance on high-quality science is critical to ensuring public trust. Regrettably, that trust is eroding. In July 2016, almost 200 toxicologists signed an appeal for the integrity in science. They were expressing concerns that precautionary regulations and policies are being presented as objective science, when, in fact, they are not. Dr. Rosenberg recently stated, "When science is sidelined from policy decisions, we all lose." The American Chemistry Council shares these concerns.

Improving agency science should not be as challenging as it has been. As you have mentioned, Senator Lankford, government and non-governmental guidance already exists. In 2002, Federal agencies were directed through OMB's information quality guidelines to ensure the quality, objectivity, utility, and integrity of information which they disseminate to the public.

Unfortunately, while most agencies have committed to meeting these standards, some agencies' scientific analyses falls short. Some examples of this are provided in the testimony ACC has provided in writing. These shortfalls are despite Federal guidance on risk assessment and peer review, and further guidance from organizations like the National Academy of Sciences (NAS), the Keystone Center, and the Bipartisan Policy Center.

The bipartisan Lautenberg Chemical Safety Act (LCSA) now mandates that EPA apply high-quality, reliable, and relevant scientific information by using best available science and a weight of the evidence approach. To date, EPA appears to imply that business as usual is consistent with these standards. Rather than explicitly incorporating the best available science and the weight of the evidence standards into the draft framework rules it is developing to implement the act, the agency has suggested that it can simply rely on existing approaches and current practices. This is of great concern to the ACC.

The peer review report from EPA's most recently released draft risk evaluation notes that EPA did not apply a weight of the evidence approach, nor did it use a systematic review process, which is a critical part of conducting a weight of the evidence evaluation. EPA simply chose the value that would provide the lowest allow-

[1] The prepared statement of Ms. Beck appears in the Appendix on page 56.

able exposure, without transparently documenting the quality of the individual studies they considered.

The good news here is that there are many potential solutions to improve agency science, and I am going to present just four.

One, improving and clarifying scientific definitions. The intent of the scientific standard is to improve existing agency practices. Agencies should provide clear and specific definitions for terms like best available science and weight of the evidence. These definitions should address not only what agencies should consider when evaluating information, but also what information agencies should present in the evaluations, forcing the agencies to show their work and present their thought process in a clear and transparent manner.

Two, there must be stronger oversight to ensure that existing guidance is actually followed. Existing guidance documents could be converted into agency checklists and agency staff could self-certify that their evaluations are consistent with these checklists. These checklists could also be used by stakeholders and peer reviewers.

Third, as was mentioned before, the importance of improving peer review practices cannot be underestimated. Ensuring that peer review panels have the depth and breadth necessary to address scientific concerns while also ensuring that conflicts and biases are addressed is critical.

And fourth, the government can play an important role in changing the incentives for grant funding such that decisions are not so heavily dependent on finding positive results, and the government standards for funding should ensure that research studies follow best scientific practices and are designed with the regulatory use in mind.

In conclusion, ensuring that Federal decisionmaking is firmly based on the use of high-quality science can be achieved through common-sense reforms that will lead to a more efficient and effective regulatory process. ACC looks forward to working with Members of the Committee to enhance approaches to ensure that high-quality science is the foundation of regulatory decisionmaking.

Thank you.

Senator LANKFORD. Thank you. Before we move into our time of questions, as is our tradition on this committee, the Ranking Member and I will defer our questions at the end.

Before we move to Senator Hassan, I want to recognize Senator Heitkamp for her opening statement.

OPENING STATEMENT OF SENATOR HEITKAMP

Senator HEITKAMP. Just a quick apology to our panel. I had a markup in the Banking Committee where a bill of mine was being considered, and I wanted to make sure it got across the finish line. So I had a chance to review your testimony and really appreciate your attendance, and I ask that the Chairman include my opening comments for the record.[1]

Senator LANKFORD. Absolutely. Without objection. So did you get your bill across the finish line?

[1] The prepared statement of Senator Heitkamp appears in the Appendix on page 37.

Senator HEITKAMP. Well, I got it out of committee.
Senator LANKFORD. OK. Out of the gate is a start. [Laughter.]
So that is great.
Senator Hassan, you are recognized.

OPENING STATEMENT OF SENATOR HASSAN

Senator HASSAN. Well, thank you, Mr. Chairman, and Ranking Member Heitkamp, and welcome to all of the witnesses today. Thank you all for being here.

I wanted to start, Dr. Rosenberg, with a question to you. In your testimony you talk about the scientific community's view of what constitutes best available science, and you also state that generally accepted standards cannot clearly be legislated without jeopardizing the kind of scientific innovation that leads to some of our most important findings and discoveries.

So I would ask you to take just a minute or so to elaborate a little bit more on what you see as the problem with legislating what should be considered the best available science.

Mr. ROSENBERG. Thank you, Senator. I think this is a really crucial point, of course, for the hearing, but in general as we think about the processes of bringing science into rulemaking.

If you legislate best available science, I believe, from being an agency scientist and regulator, that is exactly what agencies will do and they will not deviate. And so even if there is clearly a better approach, even if there is new science that should be brought into the mix, agencies will say, "My mandate is to do it this way. I will do it that way until the mandate changes."

I know that there is some rhetoric that agencies do things differently from their mandates. From my experience, you spend an awful lot of time saying, "OK, what is the law telling us we need to do?" and you really do not have very much time to do other things. If that guidance is given in statute for best available science, it will become very rigid in agency practice, and the danger there is that, science does actually evolve, quite dramatically sometimes. You want people to be able to include new information, new types of data collection that lead to new inference in their results and bring that to bear on the best policies for the Nation.

Senator HASSAN. Thank you. Another question for you, Dr. Rosenberg. You highlighted the significance of understanding scientific uncertainties, but also the importance of acting once the weight of evidence is compelling enough to justify a reasonable policy solution. For example, while there may be a degree of uncertainty as to some aspects of climate change, there is widespread agreement that global climate change caused by human activities is occurring now and it is a growing threat to society, and as somebody whose home in New Hampshire just ran out of power because of sudden extreme winds this morning, like many Americans I am acutely aware of this growing sense of extreme weather.

So why does science have uncertainty, why is it OK for scientific uncertainty to exist, and how does uncertainty play into the decisionmaking process.

Mr. ROSENBERG. Well, again, thank you for the question. Uncertainty exists not only in science, of course, but unfortunately in life, but certainly scientific evidence will always have some degree of

uncertainty. I think the importance is to characterize that uncertainty but think of it in terms of, from a policy perspective, then, what risks are we incurring?

And so uncertainty comes in many forms. As a scientist you think about uncertainty in really four different ways. You think about measurement error, which is your ability to actually measure what is happening in the world; process error, which is your understanding of the processes by which things move forward; implementation error, your ability if you implement something to actually do it accurately; and model error, your ability to characterize a process in a model which is inherently going to leave some aspects out.

Well, that is helpful for scientists to think about those types of uncertainty and they mean something different, but to a broader public, and usually to policymakers, uncertainty means you do not really know. It does not necessarily mean that. I mean, all of those types of uncertainty are different.

So if you go back to your climate change example, I would say it is not so much that there is a level of agreement among scientists as there is a very large weight of evidence, and if you look at that weight of evidence, it is quite compelling, any possible way you look at it. And sure, there may be people who say, "Well, I can identify one piece of evidence that does not seem to fit," but the weight of evidence is entirely clear.

Now you, as policymakers, are responsible for deciding how much risk we should take. That is not a science decision. I agree with Professor Dudley on that. We can say if you tell us something about risks that you believe society should incur, how the uncertainty that we have relates to those risks. Most people would say, if, in fact, climate is changing as rapidly as the evidence indicates, that the risks to many aspects of society are very high, so, therefore, you might want to take action with more uncertainty than, say, you would take in crossing the street.

Senator HASSAN. Right. Well, thank you, and that leads me to a question for the whole panel, a general one, and I have a little over a minute left. So I want to follow up on that, because Dr. Rosenberg just described the balance between uncertainty and risk to public. In New Hampshire, as you all know, like in many other States, we have a heroin and opioid epidemic that is devastating and it is a critical public health threat. And the threat, the scale of it is stunning, it is unprecedented, and we have been really working hard to get in place the prevention, treatment, recovery, and public safety measures needed to support those on the front lines of this epidemic.

But sometimes those interventions and methods we are using are newer, and while we have evidence supporting our policies, we do not always have the kind of 100 percent certainty that we would like to have to approach this public health epidemic.

So the real question is, does scientific uncertainty about something mean we should not take action at all when the risk is high, and what dangers do you think legislating a definition of best available science could pose to responding to this type of urgent crisis? Because I have only got like 10 seconds left, Dr. Dudley, I will start with you and then I will ask the others to submit a written answer to that.

Ms. DUDLEY. Very briefly, no. Uncertainty does not mean act or do not act, but I agree with Dr. Rosenberg—it is a policy question. So scientists can tell you, "Here is the uncertainty. Here is why we have this uncertainty," and it is policy officials' responsibility to say, "Here is what action I would like to take," knowing that uncertainty.

Senator HASSAN. Thank you.

Senator LANKFORD. Senator Harris.

OPENING STATEMENT OF SENATOR HARRIS

Senator HARRIS. Thank you. Thank you all for your work. I have to tell you my mother was a scientist, an endocrinologist, and, in fact, one of my first jobs ever was cleaning pipettes. I was awful. She fired me. [Laughter.]

But I do appreciate your work and the importance of the work, and particularly the importance of politics not playing into your mission and the very important role you play in advancing us, in terms of human health and also what we need to do in terms of really thinking about what we can do in terms of being innovative as a country.

So, Dr. Rosenberg, I have a question for you. This morning on CNBC, EPA Administrator Scott Pruitt stated that carbon dioxide is not a primary contributor to global warming. He said, and I quote, "I think that measuring with precision human activity on the climate is something very challenging to do, and there is tremendous disagreement about the degree of impact, so no, I would not agree that it is a primary contributor to global warming that we see." And then he went on to say, "We need to continue the debate and continue to review and continue our analysis."

Separately, according to an article in the New Republic on March 7, the EPA's Office of Science and Technology, which has historically been in charge, of developing clean water standards for the States, had on its website that their standards were guided by science. Since January 30 of this year, the reference on their website to science-based standards has disappeared.

So my question to you is that we are obviously talking a lot here, in this hearing, about sound science policy, yet one of the most important agencies that should consider science has removed the reference to science from their website. So can you talk a little bit about what you believe the role of science will play in the EPA and any other Federal agencies, and your concerns, if the importance and significance of science is diminished?

Mr. ROSENBERG. Thank you, Senator, for the question. I was not good at cleaning pipettes either, so I became a fisheries scientist instead of a Senator, I guess. [Laughter.]

The statements that you read are very concerning. I can only tell you what I believe the role of science should be. Clearly, the weight of evidence as—in my response to Senator Hassan—on not only the occurrence of global warming but also the human role in global warming, is very strong. In fact, it has been looked at by multiple studies, multiple investigators. All of the data sets indicate that you cannot really explain the data without attribution to greenhouse gas emissions, including CO2, but not restricted to CO2.

So it is very concerning to say that he does not believe that CO2 is a primary contributor, and equally, that the uncertainty is so high that we cannot act, and I think this goes back to Senator Hassan's question directly. Whether it be an opioid crisis, global warming, or many other issues, you really have to think about what is the risk. So it seems to me that the uncertainty is relatively low about whether global warming is occurring. There certainly is higher uncertainty about localized effects, but the risk of not taking action is quite high, and there are elements of understanding that risk that come from the science.

For an agency like the EPA, which is fundamentally focused on public health and safety protections, which are largely identified by scientific work, to, in any way, diminish the role of science in the agency is extremely concerning because it is public health and safety, and that is what they were set up by Congress to do, and those are fundamentally science and technical questions. How you address them, of course, is both a policy decision for you and for the Administration, depending on which policies we are talking about, but I hope we would all agree that without a very strong science basis and recognition of that science, then we would be in serious trouble with regard to public health and safety across the country.

I was asked what I make of the change in the website for the EPA Office of Science. I was very concerned about it because it referenced economically viable solutions as opposed to public health, and that certainly worries me. In my experience as a regulator, there is an awful lot of discussion about what is economically viable for whom, which part of an industry and which part of the public, and so on, but public health threats need to be front and center and predominant, and that is a science and technical exercise, by and large.

Senator HARRIS. And so we have a lot of students in the hearing room, which always makes us happy. Can you explain to me and them, and the Committee, what you believe this might means in terms of the next couple of years, and what the diminishing of science has the potential to do, in terms of policy for the next couple of years, and any long-term impact as it relates to the health and well-being of our citizens?

Mr. ROSENBERG. Well, first of all, again, I hope that the EPA continues to do what they have done for the Nation since it was created, and that is continue to protect public health and safety. And sure, I understand that people can criticize from different perspective, but fundamentally we should realize where we have come over the last 40 to 50 years, in terms of public health and safety. I live in the Boston area. Look at Boston Harbor or the Charles River or the air in Los Angeles, or whatever you would like, to decide whether that is important. So I hope the agency refocuses on using science and technical information.

I believe that there are many actions that have been proposed or called out or mentioned by Administrator Pruitt and others in the Administration that would dramatically slow the ability to address public health and safety concerns, and I think that that is truly problematic, because while we have come a long way in 40 years, there certainly are many issues that continue to arise. So I hope students are thinking, first of all, it is really important to be in-

volved in science and technology, and I have quoted you a number of times, Senator Hassan, from when we met, that, everyone here agrees that Science, Technology, Engineering and Math (STEM) education is really important. I hope we listen to the STEM-educated.

And so I hope the students here think about STEM education, and also are thinking fundamentally about what history has shown us about public health and safety changes in the country. They may not remember L.A. when you could not drive down the streets, but it did occur, and we have learned a lot from the history of agencies like the EPA, and we cannot let up now.

Senator HARRIS. Thank you. And, Mr. Chairman, I have asked unanimous consent that the article be entered into the record.[1]

Senator LANKFORD. Without objection.

Senator HARRIS. Thank you.

Senator LANKFORD. Before I recognize Ranking Member Heitkamp, I would encourage dialogue with us. We have a bill dealing with sound science, and it is not a partisan bill. That is everything, and for everyone, for either side of this. And so I would appreciate just the dialogue on that ongoing.

So, Senator Heitkamp.

Senator HEITKAMP. Thank you, Mr. Chairman, and thank you to all of the students here. I know this seems like it might be really boring, and not consistent with some fireworks that you see in other committee hearings, but I think that this discussion is so important to the future of our country. How do we take fact-based analysis, science-based analysis? And you will never separate facts from judgment.

So we are going to have different judgments about different facts, and we are going to have to analyze those. But the problem is that frequently people have different sets of facts, and different visions of science, some of which you heard today. The challenge that we have right now regarding CO2—we can have this discussion, but frequently, on things like that, the world moves around us. Right? The Chief Executive Officers (CEOs) of major Fortune 500 companies move around us, and say, in their judgment, they have looked at it, they need to do things differently in their own contexts. The public moves around us.

And that is always the challenge we have with science, because frequently, in Washington, D.C., it is politicized. We just have to put that out there, that science is in the eyes of the beholder, what is, in fact, scientific fact. And one of the things that I resist that we are doing a little bit today is we are just looking at one area, whether it is climate or whether it is, in fact, the EPA.

This discussion goes beyond that, and I want to engage first with Ms. Dudley, because we have had long conversations about the application of fact-based analysis to rulemaking, and there is a challenge here because people look at rulemaking, or these challenges, through the lens of what they believe to be fact.

I want to just give you an example. Recently—this is actually true—a basketball player suggested that the world was flat. That was in a tweet. I do not know if you saw it. And the response that

[1] The article referenced by Senator Harris appears in the Appendix on page 74.

someone gave was, "Well, we should respect his opinion." And I'm thinking, maybe not, because I thought Galileo dealt with this and was imprisoned. The Earth goes around the Sun. The Earth is not flat.

But yet there seems to be an acceptance in this country for a wide variety of reasons which say let's respect this. And so there is a widespread kind of narrowing of the lanes. You can have a difference of opinion within a narrow lane, but we cannot be swimming outside the lanes so that we accept or have a reasonable dialogue about the Earth being flat. I am just sorry. I am not going to do it.

And so the reason why I raised that is, can we, in fact, legislate that lane in a way that really gets us back to using science, but also recognizes that judgment comes with science? And I would like to start with Susan.

Ms. DUDLEY. I think that is a great way to look at it. There are some things that clearly we know, based on science. The world is not flat. There are other things where there is more uncertainty. As Dr. Rosenberg said, there is a lot of uncertainty. It is inherent in everything, not just science but in everything. And being able to differentiate what is pure science, what is pure policy, and what is in that trans-science area in the middle that we need to translate from pure science to policy, that is the trickiest thing. And if we can be more explicit about that, if scientists can say, "Here is where the science ends and here is the uncertainty around it," if we could be more explicit about that, I think we would solve a lot of the problems that you are talking about, where we are arguing about science when we really are not.

I will just quote briefly from The Bipartisan Policy Center. They had a report in 2009, on improving use of science in regulatory policy, and they concluded that "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."

Senator HEITKAMP. Yes. Dr. Rosenberg.

Mr. ROSENBERG. So I agree. I mean, this is an absolutely critical point. I believe, certainly, in the process of policymaking we should give different people their due, based on expertise. I certainly have an opinion on pretty much everything, my wife will tell you.

Senator HEITKAMP. And you would agree with me, the world is not flat. [Laughter.]

Mr. ROSENBERG. I am quite certain that the evidence is overwhelming.

Senator LANKFORD. Have you ever been to western Oklahoma? [Laughter.]

Mr. ROSENBERG. No, sir.

Senator HEITKAMP. Or the Red River Valley in North Dakotas.

Mr. ROSENBERG. So I recognize there is some uncertainty—— [Laughter.]

But I actually think that the scientific evidence and the inference that you draw from that evidence, and call science, should be done by people who are working through a scientific process, and, in fact, are scientists.

By the same token, I certainly agree with Susan, that, everyone has an opinion and we need to try to be careful so that for me as a scientist to offer my opinion about, a policy matter and I am couching it clearly as this is my opinion about the policy matter, not that it is my science that dictates a particular policy matter. And so I often am in training for young scientists and students who will say it is important to distinguish—here is the evidence and here is what I think it means, in light of the body of scientific knowledge. Now if I want to say, "Here is what I think you ought to do about it, Senator," that needs to be clearly separated.

The difficulty in the current debate, of course, is that you have all kinds of people saying, "Well, the science says this." "No, it says that." Most of them seem to be non-scientists or observers, and I think they should offer their opinion, whether the world is flat or not, but I think we should weight it and not consider it scientific evidence. That is why I continually refer to the scientific process in my testimony.

And I do not think that science is the sole deciding factor for most policies. It never is. You have an incredibly difficult job of making those societal choices. Those societal choices that you deal with every day are not a scientific decision. They are not part of the science process. All we can do is try to inform you of what the threats are, problems are, the opportunities, and certainly the consequences of certain decisions, based on the evidence that we have collected or have in hand.

Senator HEITKAMP. Well, let us talk to Dr. Beck.

Ms. BECK. Yes. It is a great question. To me, it comes down to transparency. I do not want you to trust me because I am a scientist. I want you to trust me because you have looked at my analysis, and you have been able to evaluate, if it rigorous, did it follow the scientific method, did anyone peer-review it? Right? If we can be transparent about the quality of the science and the uncertainties that come along with the science, then we can have a real dialogue about what the policy should be.

So, to me, the solution is in clarity in transparency and the strength of the science.

Senator HEITKAMP. Yes. I mean, I just think it is a big circle, and, there is consensus that this is the unknown in the middle. These are the variables in the middle. But there are scientific facts that do, in fact, establish and are widely accepted, in spite of what some person may say. Unfortunately, too often, we argue—let us take climate. For so many people, climate is not in the center. Climate is on the outside. This is known. And, in part, because I think it got politicized before there was ever an evaluation of the science. You see what I am saying? Because the public, and, I think, opinion-makers did not come to consensus on the science or on the variables before there was a lot of discussion about policy initiatives.

And so it becomes a political issue as opposed to a scientific issue, and that is the challenge that we have, which is when does it cross the Rubicon? Can we achieve some kind of analysis? And Senator Lankford and I are struggling with this. How do we respect other opinions but also narrow the focus of what we consider scientific proof or sound science?

And so with that, that is more rhetorical than anything else. I will allow Senator Daines to have a moment here.

Senator LANKFORD. Yes. I recognize Senator Daines.

OPENING STATEMENT OF SENATOR DAINES

Senator DAINES. It has been a great discussion. Thank you, Mr. Chairman and Ranking Member Heitkamp.

I just would submit, for the record, that Exhibit A and B for the flat Earth thought would be probably in North Dakota and Oklahoma—— [Laughter.]

And I will bring the contrarian opinion here, being from the Rockies of Montana.

Well, thank you for testifying before the Committee today. I guess if you want to have a fun fact this morning, I am the only chemical engineer that serves in Congress, out of 535 of us here on the Hill. There are several engineers. I get to hold down the chemical engineering caucus of one. So I truly have a fundamental appreciation for the proper role of science in the Federal rulemaking process, because it should, above all, be objective, meaning two things above all. One, data should be able to stand up to public scrutiny, and, two, it can be replicable.

When I worked at Procter and Gamble—I spent 28 years in the private sector before I came here to this new day job, where I wear a tie every day—our company used science to meet the needs of the mass consumer market, ultimately studying the needs of our consumers and rigorously developing a solution to meet that need. That is what made our business successful. It was the best type of sound and objective peer review you could ask for.

As Ms. Dudley mentioned in her testimony, science can only tell us what is but not what ought to be, and for that the rulemaking process requires human judgment, which has run amok, in my opinion, as regulators continue to conflate science with their own personal judgments.

I know the issue of climate came up. I will give you an example of that. I was in a hearing last year where we had Gina McCarthy, the Director of the EPA, come and testify. We were talking about the Clean Power Plan. And the Clean Power Plan, those regulations were going to affect the State of Montana more than any other State in the United States. It was going to have a devastating effect on our jobs—studies done by the University of Montana—our jobs, tax revenues, economic activity, double the increases in utility rates.

So I asked Gina, I said, "Cato ran the regulations through an algorithm called Magic, where you take the regulation, it then determines what the projected reduction in CO2 would be, and then projects what the impact would be on global temperature, which ultimately these regulations were means to an end, in terms of trying to reduce CO2 and reduce the impact on temperature.

And when Cato ran those numbers, the answer came back, 0.02 degrees centigrade, which is negligible. It is a rounding error. And I challenged Gina on that. I said, "Gina, I understand what we want to do with these regulations and we can quantify the impact on people. We can also quantify the impact on the science on cli-

mate." And I was hoping she would refute my data, and tell me why I was wrong and why she had other studies.

But in this limited peer review I had, from one senator to an EPA director, she did not refute the data. In fact, she said, "We need to do this because it is almost a moral obligation to show the world, and show China, and India, and other places, how we are leading in that effort," to which I responded, pragmatically, "Well, if you we cede the leadership of technology for coal-fired plants to the Chinese and to India, we will not have a better outcome. We will have a worse outcome, environmentally speaking, because we do a better job in the United States of protecting our environment, and sure, we could develop clean coal technology, innovate it, and affect the entire world."

So I think this is an example, again, where we need to get into the science and not be afraid to debate the science, debate the facts and the figures here, to ensure that we have appropriate regulations and outcomes.

Ms. Dudley, in your written testimony, you mentioned that Congress too often cedes power to regulators, allowing them to set policy objectives. An example you offered was the difference between the Clean Air Act and the Safe Drinking Water Act (SDWA), and how Congress required agencies to consider economic costs in the Safe Drinking Water Act.

So my question is, would you say that agencies are currently compliant with statutory guardrails like requirements to consider economic costs and benefits?

Ms. DUDLEY. Every President, going all of the way back to Carter, but more explicitly Reagan and Clinton, set in place standards that required agencies to look at the benefits and the costs of new regulations, and try to maximize the net benefits—get more benefits than cost, whenever possible. But it is subject to statutory constraints. The Safe Drinking Water Act is explicit and says you should look at the benefits and costs. The Clean Air Act, especially the ambient air quality standards, is not. In fact, it has been interpreted as saying that you cannot consider the costs of achieving the standard.

This gets back to what I was saying to you, Senator, Heitkamp, regarding the blurring of the lines. In the Clean Air Act we pretend that we are making our decision purely based on public health, because we are not allowed to consider costs. But nobody really thinks that is true because we do not set the standards at zero. In the Safe Drinking Water Act, there is much less acrimony, much less argument over whether the science is biased or not, because we can be clear, here is what the science says; now let us do some tradeoffs in setting the policy. And I think, to the extent statutes can look more like the Safe Drinking Water Act, that allow us to be honest about where the science ends and where the policymaking begins, that would improve the analysis and also the decisions.

Senator DAINES. Yes. If Congress were to have established these economic guardrails for agencies over past Congresses, do you have any estimate of how much cost it would have saved the economy, or how many jobs, perhaps, would have been created?

Ms. DUDLEY. There are just so few good estimates of the real impacts of regulation, either benefits or costs, but I could just give you an example. An EPA rule—not the Clean Power Plan but another rule that affected electric utilities, the Mercury and Air Toxics Rule—the Supreme Court sent that back to EPA because that statute set standards that are appropriate.

Senator DAINES. Yes.

Ms. DUDLEY. And the Court said, "It's not appropriate to have $9 billion in costs to achieve hundreds of thousands of dollars in risk reduction." So, in that case, the Supreme Court said, when the statutory language says appropriate, it does mean this balancing of benefits and costs.

Senator DAINES. Yes.

Ms. DUDLEY. But yes, if Congress were more explicit, I think that $9 billion you would have been able to save.

Senator DAINES. Yes. That is a pretty good number. Well, and I think you mentioned the Clean Power Plan. Certainly a little over a year ago the Supreme Court intervened, as well, on that.

I want to talk about the redacting PII. I think that came up for public access.

Oh, I am out of time, I see, Mr. Chairman. Are you OK?

Senator LANKFORD. I will ask for unanimous consent to give you 12 more seconds. [Laughter.]

That is fine.

Senator DAINES. I am having so much fun here, I am looking at——

Senator LANKFORD. It is all right. Go ahead.

Senator DAINES [continuing]. The red light was on here, Senator.

Regarding redacting PII for public access, Mr. Rosenberg spoke in his testimony that the public should not have access to scientific information used for regulations in order to maintain confidentiality. We do not use reams of paper anymore. We do use Excel and other forms. Dr. Beck, cannot sensitive information be redacted, since most data is electronic?

Ms. BECK. Yes. I think sensitive information can be redacted, as well as protecting confidential business information, trade secret information. There are ways to share the data without sharing these important details.

Senator DAINES. So it seems that researchers, can data mine, they can slice-and-dice numbers to perhaps draw their preferred conclusions. And back to that important point of peer review and scrutiny, do you believe there is wisdom in numbers on this one, and public scrutiny of scientific information could perhaps foster better regulatory rules and outcomes?

Ms. BECK. Reproducibility, to me, is critical. Right? So often times you need the underlying data to actually reproduce the analysis. We have had situations at the American Chemistry Council where we did not understand an analysis that was presented by EPA, and at first we worked with the journal researchers, to try to get that data. We worked with the agency to try to get that data. Eventually—and this took years—we were able to get the data through a data transfer agreement with the National Institutes of Health (NIH), and they protected whatever information needed to be protected, and we were able to conduct a re-analysis of that

data. And that re-analysis came out differently than the agency's analysis, so now we can actually have that important scientific dialogue to understand the data. So I think that access to information is really important.

Senator DAINES. Thank you.

Senator LANKFORD. Thank you. So this whole conversation is the challenge that we have back and forth between, we want to get good information, whether it is science, or whether it is facts, or research, or whatever it may be, in any area, because the policymakers need that, and the agencies need that. So the conversation today is really all about how do we get that balance between getting good science, but understanding we are not asking the scientists to be the policymakers, and in a strange way, we ask the Federal Bureau of Investigation (FBI) to go research, to go get everything together, and then they give all of their information to the Department of Justice (DOJ), and the Department of Justice determines whether to prosecute. The two are kept separate, so you do not have the people doing all of the research and all of the gathering of information also making the final decision.

In a strange way, science and policymakers are the same way. We ask folks in science, "Do the research. Get the information." But we have to make some final decisions on this on how to be able to balance it, but we want to make sure that is done in the same in the agencies. So the challenge is, how do we pull this together?

Professor Dudley, you made a comment that I would like to be able to highlight more. You did not talk about it much, during your oral testimony, but you did in your written testimony—about risk assessments, and getting multiple options and opportunities, knowing that science does not always agree on some things. So giving kind of a larger window view of that. Can you go into a little more depth on that?

Ms. DUDLEY. Yes. I think that would be very important, and because the model——

Senator LANKFORD. Describe what you mean by the risk assessments, and then take us through it.

Not everyone in the room has read your written statement.

Ms. DUDLEY. Well, you are missing something. [Laughter.]

In developing, especially environmental and public health regulations, we go through a process where agencies assess the risk and then they try to manage the risk. And back in 1983, the National Academy of Sciences said, conceptually, we should think of those as two separate things-the risk assessment process and the risk management process, because the risk management process takes other factors into account—the economics, law, what other regulations are in effect, political goals—whereas the risk assessment is the scientific inputs. Again, risk assessment tells us what "is" versus what "should be."

But I think we have all talked about this. It is important to recognize that even in that risk assessment phase, it is not as straightforward as "the Earth is flat or not." There is a lot of uncertainty. There are different models that predict different things, different data available, different assumptions used to apply those data to the situation that we are concerned about. And that is where a lot of these hidden policy judgments can get hidden.

So one of my recommendations—and this is not my recommendation but it comes from other people in this field—is that it would be better if the scientists were to lay out, using this set of assumptions, we get this number, a different set of assumptions provides different numbers. Lay that out, and then the policymaker can look at those different estimates, and that is the policymaker's job. I mean, it is your job. It is the head of EPA's job. Knowing this is a range of estimates, what is the right policy?

Senator LANKFORD. You have worked with us before, at OIRA, and you are familiar with the process. What would that look like, as far as an executive action or a codification or—how would you consider something like that fitting into how we do our government?

Ms. DUDLEY. That is a great question. It is so much harder to put it into a statute.

Senator LANKFORD. Correct.

Ms. DUDLEY. So in 2007, we issued—I forget what it was called—the Office of Science and Technology Policy and OIRA issued a joint paper that Ms. Beck was very involved in, on risk analysis in general. Not just the regulatory process. And that laid out some things that really had been based on a set of guidelines issued in the Clinton Administration. Those have withstood the test of time. I wonder whether that would be something that might be worth fleshing out a little bit more.

Senator LANKFORD. OK. That is interesting to be able to note.

Dr. Rosenberg, you have mentioned a couple of times that you feel like it will especially squash science and innovation if best available science is codified at some point. So I want to delve into that a little bit more, of the why, because as I read through it, my competitive nature says if it is the best available science and it is new science coming up, it would drive them to be able to show the validity of it, multiple locations to be able to see how it has been used, and to show this science, this technique, this modeling is better than that modeling, and to be able to push them toward that.

You seem to imply that if we do best available science that will actually push all innovation out and only old science, that has been well-tested and has, as you have mentioned, weight of evidence from being used over and over again, will be the one that is used. How do we hit a balance on that, because this is not theory anymore? This is already being codified by Congress. It is in the Toxic Substances Control Act (TSCA) Bill already, of a standard for best available science. It has been in Executive Orders (EO) for a very long time.

Mr. ROSENBERG. Thank you, Mr. Chairman. I think in TSCA and in other bills, there is some description of process, but if you codify, and, particularly, then becomes judicially reviewable, then people will retreat back to what is the most cautious interpretation in many cases. That is what I believe agencies will do. They will be careful about the information that they consider as part of that weight of evidence, and that means that you would be less willing to consider new information or information coming from other sources that might be critically important.

I believe that you can certainly, through your oversight responsibilities, hold agencies to account that they have used a very effec-

tive process. My concern is, in legislation, then it becomes a much more rigid vehicle. So it is not that I do not think that there is no such thing as best available science. I described what I think the hallmarks of best available science are in my testimony.

I do not think it is as rigid, and if I can refer to Professor Dudley's comments on risk assessment, as there is a good example. The view of how you do risk assessment in different fields has, in many cases, changed through time. You could legislate exactly how you should perform a risk assessment, including how do you paramaterize the models, if you like. Now you are getting down deeply into how do you actually conduct the science.

On the other hand, there may be much better ways to approach that problem that emerge next year, the year after, or in a different field, and you want to make sure that people are able to do that and not say, "That is not how we do it."

In TSCA, it seems to me, and you are obviously an expert on TSCA, but there is an opportunity to use a structured system, but it does not apply across many other fields. Even the term "replicable" or "reproducible"—what does that mean to me as a scientist who does field studies on marine biology?

Senator LANKFORD. You have to wait for that same fish to swim by again, in the same spot. [Laughter.]

Mr. ROSENBERG. Yes. I would ask the fisherman to catch him again.

Senator LANKFORD. Yes. We need to know—and I think the oversight portion of this feeds into what you just mentioned, that when people are looking at it, it is not just closest science, or the sciences in the cubicle next to you that was most convenient for the agency——

Mr. ROSENBERG. Absolutely.

Senator LANKFORD [continuing]. Or it is someone that I graduated with, but there is an actual opening up to say, let us ask the broader question. Let us ask the entire science community. And going back to your comments earlier, about peer review—it seemed like you were very engaged in the issue of oversight on peer review process—to be able to ask the broader question, for us, as policymakers, to say, have we looked at a broader group of science? And just because you used them last year does not mean that this is the best available science this year. It could be someone besides your brother-in-law that has the best available science this year. Let us open this up.

Mr. ROSENBERG. I entirely agree that the mechanisms for ensuring that the science is not only best available but—and is independent, are critically important, and those are peer review, disclosure of conflicts of interest, ensuring that you are bringing in information from other fields, all of those things, that are done in understanding that all of this science is scrutinized through a public process as well.

Senator LANKFORD. That is the ultimate peer review.

Mr. ROSENBERG. There are many aspects of peer review that occur in a regulatory process.

Senator LANKFORD. But the question is, when you are going for best available science—and I am going to go to Senator Carper here in just a moment—but when you are going at best available

science, our goal of that, and what I hope we can do, and what I hope we did in TSCA—TSCA was so well-received it was voice-voted here in the Senate, as putting in statute, for the first time, something that has been in executive action for a long time, to say let us look at how do we open this up to as many people in the science community as we can, and ask the EPA, in this setting, to be able to look specifically at who you have used, but is that the best method to use, and go research that out, and go ask the real questions of it, and then to be able to put that in that language, and also, as you have talked about before, the weight of evidence, which we will come back and talk about in a moment again. That becomes extremely important.

What we are trying to figure out is, if this works in TSCA, does it work in other instances, to ask for the data, to ask for the method, to ask for the model, to do the transparency, to do, as you have just mentioned, for the public to be able to look at it and do the ultimate peer review, and to be able to evaluate and ask the hard questions that need to be asked, and know it is going to stand up, that the scientists are willing to be able to say, "This is good science. We put our science out. Policymakers made their decisions based on that," but at the end of the day, people can look and review the science. And so if you disagree with a policymaker, you can also go back and ask them, "Where did you get this thought to come from?" and you can also go back and disagree with them, and argue through the facts as well.

Mr. ROSENBERG. All of those principles I agree with, but I would just add you also need to make it workable, because, of course, you cannot wait to make a decision about a toxic chemical, about a resource or anything else, until you have such broad engagement. And there always, of course, will be somebody with a contrarian view.

Senator LANKFORD. Sure.

Mr. ROSENBERG. And so it does have to be a workable system that agencies can actually manage. Otherwise, they will not actually carry out their mandated results.

Senator LANKFORD. I could not disagree more, but even in emergency situations, where we have seen agencies step in and say, "This is so vitally important. We need to engage right now for public safety and health," there are mistakes even in that, and we need to allow for humanity to exist.

One of the most obvious examples was recently, when agencies rushed in after the fertilizer plant explosion in West Texas, and it was immediately, we need to make these massive changes around the country, and then, 2 years later, the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) finished their investigation and discovered that was not an accidental explosion. That was an intentionally set fire. Well, that changed everything on the premise, that for 2 years the agencies had run with a false premise.

So I understand everyone makes mistakes in the process on that, but good oversight helps us in the process as well, and a good set of boundaries for it.

We will come back to this. I want to recognize Senator Carper.

OPENING STATEMENT OF SENATOR CARPER

Senator CARPER. Thanks. Thanks so much, Mr. Chairman. Senator Heitkamp, good morning. Nice to see you. To our witnesses, Susan, welcome back. You have been here before. You should probably pay us by the appearance. [Laughter.]

Dr. Rosenberg, Dr. Beck. I have a specific question for Dr. Beck. Before I do, I applaud our Chair and Ranking Member for holding this hearing. We are grateful to our witnesses for coming.

I have a question for Dr. Beck, but before I do that I would just like to ask Susan if each of you just take maybe 30 or 45 seconds, since I did not get to hear your testimony, and just maybe give me what you thought would be a point that we should really walk away from here with. Give us a good nugget or two.

Ms. DUDLEY. For me, I think it is that science is essential for informing regulatory policy, but it cannot decide regulatory policy, or policy, in general, and that there are other disciplines that are also important. And so often, when people accuse others of politicizing science, they really are talking about decisions that science can inform, but not decide. And if we could do a better job of being clear where the science ends and where the policy begins, I think it would open up to much more rational debate on the policy side, and we would not impugn science inappropriately.

Senator CARPER. All right. Good. Thank you. Dr. Rosenberg.

Mr. ROSENBERG. I would actually agree with that. I would also say that we should—when we are talking about concepts such as best available science, we should really focus on the process of developing that science. It is not a matter that everyone goes and redoes the analysis, that it is the science through a credible process, contributes to a weight of evidence.

And then there is a judgment call on a policymaker's side—is the weight of evidence enough to take action? But we should trust that there is a strong science process and continue to strengthen it with elements such as scientific integrity policies and transparency policies.

Senator CARPER. Good. Thank you. Dr. Beck same question.

Ms. BECK. So I agree with Susan Dudley about—both of them—about the separation of science and policy, and I think this is why it is important that we be really transparent about the quality of science. And the confusion about whether or not to codify a definition is—I just do not understand it. I think that people should commit to using an approach—that uses a clear criteria to evaluate studies, to ensure they are peer-reviewed. It does not put the finger on the scale for any particular study, but ensures that at that period in time, you are looking at all of the evidence and using the best evidence to define the science. And then you move it to the policy arena.

Senator CARPER. Would it be safe to say that the three of you agree that we should not be blinded by science?

I think everybody nods yes. Thank you. Thomas Dolby would appreciate you saying that.

Dr. Beck, my colleague has been talking about Toxic Substance Control Act and his compadre from Oklahoma, Jim Inhofe, following David Vitter from Louisiana, Tom Udall, myself, and a bunch of others, worked for years to enact the full legislation. And

I think if they ever remake the filmstrip or civics video about how a bill becomes a law, I would nominate TSCA for the Oscar, and say—it took a long time, but, in the end, it was just really nicely done.

The reason it was important that Congress act last year, was that TSCA had been essentially a broken law since 1991. I think some would say even before that, where an industry, I think in 1991, successfully sued to overturn the Bush Administration's proposed ban on asbestos. And they were able to do that because the old law required EPA, as you may recall, to choose the "less burdensome" regulation for industry, and industry argued that the EPA had not evaluated the costs and the benefits of all possible alternatives to a ban, even though EPA had spent, I guess, a decade or so writing the rule and had prepared thousands of pages of analysis.

The EPA concluded that TSCA was unusable, and for decades it could not regulate the safety of chemicals it knew to be dangerous.

Would you agree that the requirement that EPA select the "least burdensome" regulation is a major part of why old TSCA was unusable and a major part of why we all worked so hard together to reform it, Ms. Beck?

Ms. BECK. Yes, that language was very problematic.

Senator CARPER. If you want to say more that that language was very problematic, you can.

Ms. BECK. Well, the language does not——

Senator CARPER. We do not charge you for testimony. We do not pay you either. [Laughter.]

Ms. BECK. The language does not exist anymore, right? I think there was full agreement that the language confused the science and the policy. So now you have an unreasonable risk standard in the new Lautenberg Chemical Safety Act, which is based purely on the evaluation of the science. It looks at the hazards and the exposures under very specific exposure conditions, and then it makes a science determination. And then separate from that, there will be some risk management steps that consider costs and benefits, but there is no requirement on the agency to choose the least burdensome.

Senator CARPER. OK. When we wrote the new law over the last couple of years, we told EPA to—try to first figure out whether or not a chemical was dangerous, and then to consider the cost when the agency was deciding how to protect people from whatever risk the agency had identified. We did not tell EPA, though, that it had to study the costs and benefits of every possible regulation, and we did not tell EPA that it had to choose the cheapest option. We told EPA it had to protect the public against unsafe chemicals and consider costs when it did so.

Let us just say, for a moment, that EPA proposes a regulation under TSCA that costs industry, we will say, a billion dollars. A lot of money. And industry tells EPA, during the required comment period, that there is an alternative that will protect people just as well, that costs only a million dollars. A million versus a billion. Is it not true that the Administrative Procedures Act (APA) requires EPA to consider and respond to industry's views on cost when they write the final rule? And that could be, again, you, Dr.

Beck. Is it not true that the Administrative Procedures Act requires EPA to consider and respond to industry's views when EPA writes the final rule?

Ms. BECK. So I am not an expert in the Administrative Procedures Act, but yes, the rulemaking process does require that the agency consider the public comments and provide responses to those comments. It does not require that the agency accept those comments but they have to consider them, discuss them, and explain how they were considered.

Senator CARPER. OK. Thanks.

Ms. BECK. Yes.

Senator CARPER. Is it not also true that if EPA ignores that cheaper, equally protective measure in its final rule that industry could also sue and overturn the rule, under the Administrative Procedures Act? And if you do not know the answer to that question, maybe one of the other—your colleagues would. Dr. Rosenberg. Susan?

Mr. ROSENBERG. Well, it is probably more Susan's area than mine, but I would say that frequently happens with a claim that it is arbitrary and capricious, which is the language of the Administrative Procedures Act, and that was drummed into my head when I was a regulator, because that is in every challenge to a regulation—you have been arbitrary and capricious, which goes back to the role of science. So, yes, that is what APA does. It gives you that opportunity.

Senator CARPER. Yes. Susan? Same question.

Ms. DUDLEY. Yes, that is right. Anybody could sue if the agency did not base their final regulation on the material in the docket, which would be comments from the public, the data they have, et cetera.

Senator CARPER. OK. Good. Who succeeded you at OIRA? Was it Cass Sunstein?

[No audible response.]

One of the things that President Obama asked him to do was to—I do not know if it had been done before, but I think they called it a look-back—to look back at regulations that had been adopted, in some cases many years ago, that may have served their purpose but did not anymore, and to see which ones should be saved, which ones modified, and which ones gotten rid of.

I have read that that was a pretty successful endeavor. I believe it went on throughout the rest of the Obama Administration. Do you have any recollection of that?

Ms. DUDLEY. You are right. It was actually something that every President since Carter has asked agencies to do.

Senator CARPER. Yes.

Ms. DUDLEY. And yet they really do not do a good job of it, for several reasons. One is that the incentives are not there. It is much more interesting to look at the next problem to solve rather than looking back, and even regulated parties often are not interested, because—especially if there are investments they had to make, the last thing they want is for the agency to say, "Oh, never mind. We should not have done that," because then their competitors will have an advantage.

Senator CARPER. Yes.

Ms. DUDLEY. But it is also hard to do. So it is not——

Senator CARPER. Did you do it while you were running OIRA?

Ms. DUDLEY. Yes, and so I was at OIRA for the last end of the Bush Administration——

Senator CARPER. Yes.

Ms. DUDLEY [continuing]. So I was actually wrapping up things that had been begun before me, toward the end.

Senator CARPER. You were there on the clean-up?

Ms. DUDLEY. I was there for the clean-up. I was finishing things.

Senator CARPER. Oh, that is good.

Ms. DUDLEY. But one of the things that I think about retrospective review is that it is not just to see what does not work and to rescind and reduce costs. It is to find out whether our estimates of the risk reduction benefits were accurate. It is part of the scientific method that requires hypothesis testing, gathering data and testing your hypothesis.

So I think it is very important. There was a bill that Senators Lankford and Heitkamp introduced last year that would have required agencies, when writing a new regulation, to plan for how they would review it, 5 or 10 years down the road. That, I think, would be huge for the science, the risk assessment that goes into regulation——

Senator CARPER. Right.

Ms. DUDLEY [continuing]. Ex-ante as well as ex-post.

Senator CARPER. You are not just saying that because he is sitting here, are you?

Ms. DUDLEY. No. Not because I am huge fan of both of yours, but no, that is not why.

Senator CARPER. Thank you. And the converse is true.

Thanks so much for being here and for your help. Thanks. Thanks, Mr. Chairman.

Senator LANKFORD. No, thank you, and can I finish up this conversation as well, when we were talking about finishing and closing and cleaning it up, and we will have about another 10 minutes or so if you all are kind of wondering on time, unless we keep going, and then it goes until one. We will see.

My question for you is this issue of retrospective review. How does that work in the science, and I am still thinking about the legislative side of this. Let us say you have a regulation that is a $100 million-plus regulation that comes out. Seven years later you go back and look at it. It is not accomplishing what you want. The science has moved, as Dr. Rosenberg, you have talked about often. The science continues to develop in research. You have better measurement tools and you figure out your hypothesis did not work. How do you do a retrospective review when there is also a scientific opinion that is sitting, that may, at that point, be 10 or 12 years old? Are you talking about a retrospective review that would also include re-evaluating the science again, or just looking at the numbers, or trying to evaluate that?

Ms. DUDLEY. I actually think thats one of the under-appreciated advantages of doing better retrospective review would be evaluating whether our scientific predictions were right. So it is not just valuable for the regulations that we issued 10 years ago, because it may be too late to change those, but it helps us the next time

we issue a regulation, we will know which of our assumptions maybe were not right. So I think it will improve the science if we could do a better job of it.

Senator LANKFORD. Right. And it is the same thing whether it is economics or whether it is science of any type, that you get a chance to note, this is what we estimated, this is what we thought would happen, this is the model, and then we look at it 5 years later and say, is the model proving to be correct, and sometimes you have not had enough time to be able to evaluate it, and sometimes you have.

Ms. DUDLEY. It is just an essential part of the scientific method.

Senator LANKFORD. OK. I want to get into this issue of weight of evidence. Dr. Beck, you and Dr. Rosenberg both brought this up significantly, both in written comments and in oral comments as well, by dealing with the weight of evidence. Dr. Beck, you mentioned several spots that you had some frustration already with the EPA not looking at weight of evidence. I would like to get a chance to talk about that and figure out how we address that, because that is one of the things in TSCA, specifically in statutory language, that this Congress said, "no, we want EPA to look at weight of evidence in this role, and to be able to figure out where that comes from."

So, Dr. Beck, if you want to talk about how you see that being applied right now and then let us try to figure out how we actually deal with this.

Ms. BECK. Yes. So in the Congressional Record associated with the TSCA rulemaking, there is a definition for weight of evidence, and we would like to see the agency simply adopt that definition. It basically would commit them to looking at the studies and evaluating their strengths and limitations using a systematic review process which is a standardized process for essentially evaluating evidence, providing sort of the recipe for how you are going to bake your cake before you bake it. Everybody knows the criteria that you are going to use, the plans that you are going to use for analysis. You put that up front. You are clear about how you are going to collect your literature and evaluate your literature and do the analysis. So once you have evaluated the strength of the evidence, right, the individual strength of each individual studies, based on the quality of those studies, you weight it all and you make your determination.

So that is the definition to us that seems so straightforward and so consistent with the scientific process, we think it should be adopted into the regulations that EPA is writing, to implement TSCA.

Senator LANKFORD. OK. Are there other definitions out there for weight of evidence that you would recommend, other than what was done in the Congressional Record?

Ms. BECK. The term has been confused over the years. Some people use a strength of evidence approach. That is very different and we do not support a strength of evidence. That is how many studies are positive, how many are negative——

Senator LANKFORD. Right.

Ms. BECK [continuing]. And oftentimes people discount the negative studies. We only think the negative studies should be dis-

counted if they are of bad quality. If they are of high quality they should be considered equally.

So, to me, the cleanest approach is to adopt the one that the Congressional drafters had, and there was support for that definition in the House language as well as in the Senate language.

Senator LANKFORD. OK. Dr. Rosenberg, any comments about just the weight of evidence?

Mr. ROSENBERG. Well, I would just say that the weight of evidence is more than just tallying up the number of studies, and I do not think that you can equally weight every study. And so I do not disagree that there should be clear guidance from the agency, in terms of—so that people can understand how the agency will interpret information going forward. But I would caution against saying, well, if it is a credible study then everything gets equal weight, because that is not how you would do it as a scientist, certainly. You would consider the uncertainty. You would consider a lot of factors around the study and weight things appropriately.

Senator LANKFORD. Back to the range of options, Dr. Beck, you had mentioned one of your proposals, grant funding not based on positive outcome.

Ms. BECK. Yes. So, in the scientific world there is this concept of publish or perish, and that if you do not have a strong publication record you are not going to get promotions in academia and you are not going to get tenured positions. And in the journal world, there is an incentive to only publish data that are positive. People do not like to publish negative studies. People have talked about creating journals of negative data so that people are not reproducing the same studies that fail over and over again because the public does not know that they fail, because nobody is publishing them.

So if there was a way to, at least within the Federal Government, to encourage the publication and the presentation of negative data, that would be extremely helpful.

We are aware of cases, for instance, at the National Institute of Environmental Health Sciences (NIEHS), where they have done some studies that are actually negative, and we have been talking to them, can you please publish these data? These are important studies. And at this point in time there are not incentives to them to release negative data as much as there is to release positive data.

Senator LANKFORD. But when you talk about grant funding based on it, the grant funding should be, at the beginning of it they do the study, not at the end of it. Somewhat this sounds like——

Ms. BECK [continuing]. Yes——

Senator LANKFORD [continuing]. You want to make sure your study ends up positive at the end if you have got grant dollars, if you want to get more grant dollars.

Ms. BECK. If you want to get more grant dollars. That is correct. You have a 5-year grant and you want to get your grant renewed, or you want your center renewed, you want your center to have positive findings or it is not likely to get renewed by a Federal agency.

Senator LANKFORD. So is it the fear that the science either gets limited—there were, for lack of better terms, 10 things we learned

not to do, one thing we learned to do, and we only published the one because you want to show positive, or is your fear that the science is going to make sure that they try to push it and steer it toward something positive, regardless?

Ms. BECK. Well, it is actually both. The official term is publication bias, and that is that what exists in the literature are mostly positive findings. So then when people go to evaluate all of the evidence in totality, they are going to have a lot more positive studies than negative studies, and then what you cannot evaluate does not get to inform your regulation, right, so the positive studies are then informing the regulation and the negative studies, which are not published, are not known.

Senator LANKFORD. OK. Dr. Rosenberg.

Mr. ROSENBERG. Just very briefly, while I agree that occurs, it is not restricted to grant-funded research. Of course, industry does the same thing. Clinical trials are the classic example of that. You do not put forward the clinical trials that did not show the positive effect. And so there is a problem of those incentives. It is all across industry and it is also in academia.

Senator LANKFORD. OK. Both of you also mentioned the issue about peer review, and if there is a legislative—in fact, Dr. Rosenberg, I think you said if there is an area to address in legislation that peer review process or trying to improve that was one of the areas. But regardless of whether it is legislative or not, what would be your recommendations on trying to deal with the peer review process, or how we label this, this is a peer-reviewed study, and still determine the quality of that?

Mr. ROSENBERG. Well, I think I said that both scientific integrity and peer review were important areas for progress. I think the independence of peer review is critical, where you are actually getting the peer reviewers, and the breadth of that peer review. This is actually not the same as a peer review you do for academic journals, where, there is a limited number of reviewers and then you can move forward with publication. Obviously, in regulatory work, you have to have a more intensive process, and that goes to the selection of peer reviewers and so forth.

I think, from a legislative perspective, it is important that agencies be clear about what their peer review process is, and how they select reviewers. We should be careful that reviewers are not representatives of different interests, so the idea that has been in some quarters in science advisory boards, that you should have representational members. That is a bad idea for peer review. You should be there because of your expertise in particular areas and you contribute to the review. There are questions in regulatory review about whether it should be anonymous review or not. The most important thing is that there is a clear and transparent, process for how we are going to conduct peer review. People can know that we did it——

Senator LANKFORD. So let me press on that a little bit. When you are talking about representational review, do you have an issue, for instance, if you were doing—let us say we are testing safe drinking water, that EPA is both doing their own sample with their own agency folks. Industry that may be nearby that they know that they are suspect, should they be able to be at that site, be able to

pull from that same—if you are going to pull 10 gallons of water out and be able to examine it, they pull a quart out of it as well, out of that same group, so they are able to run it through their lab? So you have multiple competing labs all checking it, because as you know well, there are some differences in all of the testing there. Do you have a problem with that type of peer review, where it is a group that could be affected by it, but they would have to be there onsite to be able to make sure their sample is consistent?

Mr. ROSENBERG. So I do not have any problem with having, as you describe, different entities involved in the sampling. What I would say is that if you are going to then apply peer review, which is independent, outside experts who look at the results, and look at the methodology, and do all of the things that you do in peer review—this is not, again, the raw data, but how it was done—that that be done not just for the agency analysis but it also be done then if the affected industry says, oh, well, we got different results——

Senator LANKFORD. Show your data.

Mr. ROSENBERG [continuing]. It should have exactly the same peer review standards.

Senator LANKFORD. Yes.

Mr. ROSENBERG. The difficulty I have had in regulatory settings is that I might go through, 20 public meetings on scientific analysis for, again, marine resources. I know you have many of those in Oklahoma. And someone else would stand up and say, "Well, my results are different." You have absolutely no idea whether that has been reviewed or who has reviewed it. It is not meeting the same standard at all. So you have to compare like with like.

Senator LANKFORD. Yes. You will be glad to know that Oklahoma has more fresh water shoreline than any other State in the union.

Mr. ROSENBERG. I am really happy to know that.

Senator LANKFORD. We dig a lot of ponds. [Laughter.]

So we do that. We know how to store our water.

Let me ask for your quick response on that as well, and then I want to try to move on to a final question.

Ms. BECK. Yes. Peer review is an area that I think could benefit from a lot of improvements. One of these issues relating to representative, equal review of all data is funding. I listened to a peer review panel where there was a very good study funded by industry, and when it came up one of the peer reviewers said, "Wait. Was not that funded by industry? We are not going to consider that." It was just completely discounted, simply based on its funding, and there was no evaluation of the quality of the data.

So, again, I think these peer-review panels, of course you need to address conflicts and biases, but you need the breadth and the depth and the expertise. If you are reviewing something about a manufacturing process and you have nobody that understands the manufacturing process, I do not think that peer review is going to end up being very good.

In the FDA, they have ways of having experts that might have conflicts on panels to help educate the panels, but they do not vote. Senator Carper referred to the Oscar-winning TSCA rule. The TSCA legislation actually requires different representations on the review panel, and those representations include animal welfare,

labor, industry. In putting that panel together for the industry representation, EPA has chosen two people from the pharmaceutical industry. These people do not understand the chemical manufacturing process and TSCA does not regulate pharmaceuticals.

So I think you have to reach a point where you ensure that you have the right expertise and breadth to do a high-quality peer review.

Senator LANKFORD. Yes, which makes it a challenge after the fact.

Ms. BECK. Yes.

Senator LANKFORD. The TSCA language on the science section, do any of the three of you have an issue with that, how it was written for that area, as much as you know the language? I am not going to ask you to know every word of it, but as much as you know. Dr. Beck.

Ms. BECK. So I would just say that that language, it is consistent with what is in the information quality guidelines. It is very consistent with what is in the Safe Drinking Water Act. It should not be new to the agencies.

Senator LANKFORD. No, it has been in existence for a long time——

Ms. BECK. Yes.

Senator LANKFORD [continuing]. As Executive Orders and other actions.

Ms. BECK. It is not new. It is around, so it is actually nice to see it in there, and we hope that when EPA finalizes their framework rules under TSCA they will commit, to meeting those standards in their rules.

Mr. ROSENBERG. Chairman, I do not know the language in that little detail. I would just refer back to one comment that Dr. Beck made, about representation on a peer-review panel. That is exactly the problem of having people who are there to represent a particular interest. They are no longer peer reviewers. If they are there because they have particular expertise, I do not have a problem.

Senator LANKFORD. Right.

Mr. ROSENBERG. But if you say, "I am here as an industry reviewer. I am here to represent the interests of industry," or nongovernmental organizations (NGO's), then I have a real problem. That is not a peer review to me.

Senator LANKFORD. Right.

Ms. BECK. I agree with you. It should be expertise.

Senator LANKFORD. Right. So let me ask this question. Is there an issue with trying to get the data, the models, and the methods out, so when an agency concludes their work, you can ask the practical question, "You came to this conclusion as an agency head. You based it on this report. Can we see—with private information excluded, obviously, and redacted—the data, the models, and the methods" to be able to come to that? Susan Dudley.

Ms. DUDLEY. I think that is essential, and I will just read from Science magazine which requires that now for their articles. The editors, when they made the change to make data available, said that "when the greatest number of creative and insightful minds can find access and understand the essential features that led to

the collection of a data set, the data reached their highest potential."

So I think that is an essential element of the transparency that you mentioned in your opening statement.

Senator LANKFORD. OK. Dr. Rosenberg.

Mr. ROSENBERG. I do not agree that the raw data is needed and I do not think that is what Science requires, in most cases. At least whenever I publish there they do not ask for the raw data. I think the confidentiality is not just for public health records. It is also confidential business information, intellectual property. It gets very complicated quickly.

Again, for most studies, you are not reviewing the raw data but you are doing exactly what Susan said. You are looking at how was the data collected, what is the provenance of the study, models, and so on. Does that mean that we would never consider results from a proprietary model, including the magic model that one of your committee members cited? For evaluating the Clean Power Plan we should not consider that because that model is proprietary. So there is a whole range of information, not just public health information.

I think that to the extent that data can be released, fine, but I do not think that that should be the requirement, and if you cannot do it, for multiple reasons, therefore, you do not move forward.

Senator LANKFORD. How do we have transparency without knowing the data, or without knowing the process of how it was put together? Because as you know well, the variables within data and the assumptions that underlie that can vary dramatically.

Mr. ROSENBERG. I have absolutely no difficulty with describing, in detail, how the data was collected. The data collection process is part of something I review in every study that I look at. The modeling process is something that I review in every study that I look at, because I tend to mostly review modeling studies. I do not review the raw data.

Now, sure, some people may want to do alternative analyses of that raw data. It is almost inevitably going to be for regulatory matters, industry. Nobody else would have the capability of doing that. But again, then, interpreting those results, unless they are put back into exactly the same peer review process that the agency used, is almost impossible, and the difficulty then is you have gotten into a very difficult, very long process of review with almost no end, because anyone putting in a new process starts a new round of peer review and you just stay in peer review forever.

So I think you need to be realistic about what the information will be. The information to review is the details of that process of how that data was collected, certainly, and all of the other elements of the study, as I indicated in my testimony.

Senator LANKFORD. OK. Dr. Beck.

Ms. BECK. I noted this is in my testimony. The public trust is eroding in science. There are articles in the Washington Post about how 50 percent of the science that is published is, maybe false and not true. And I am not saying every study is unreliable, but if you want to have trust and confidence in your regulatory decisions, you need to be as transparent as you can absolutely be about that un-

derlying data, so that everyone is on the same page and can have a scientific dialogue. It helps to build trust and confidence.

So proprietary information, private information, all that needs to be protected. There are ways to protect proprietary information in models while letting other people look at those models. I think there are legal ways data-sharing can happen, and to the extent that the scientific community can improve that, the public confidence in the science will be greatly improved and confidence in regulatory decisions will be improved.

Senator LANKFORD. Yes, that is a balance, obviously. We want people to be able to do their research, to be able to protect their data. They have paid for it, they have worked through the process, unless it is the Federal taxpayer that paid for it, and that is a whole different set of issues.

But the challenge that we face is trying to trust it and to say "how can we get a chance to do a good evaluation," even things that are given the tag "it was in a journal," "it was published," or "it was peer-reviewed."

One of my favorites studies, when we were going through and doing the preparation for all this, and the research, was finding Dr. Bohanan's tests from Harvard, the biologist there, where he wanted to find out how the scientific journals went, and so he created a completely bogus study, with bogus modeling and everything else, and presented it to 300 different scientific journals, and 157 of them accepted it. And you think, OK, there is a challenge here, even within scientific journals, on how they accept what is fact and what is, at that point, completely bogus information. So we have to be able to guard that, and that is part of gaining public trust.

The one thing I would like to do is be able to maintain this conversation. We are seeking a way to be able to solve this legislatively. We do not want to overreact and what it has done and able to squash the future of science, or to be able to compel people to not do research or to be able to put proprietary information that should not be put in the public domain not in there.

I would tell you I serve on the Intelligence Committee as well. We deal with a tremendous amount of redacted information and a tremendous amount of research that can be put aside with private information. So I think there are ways to be able to accomplish some of this without putting people's private information or proprietary information at risk, so we can still gain trust.

So I would appreciate your feedback as we walk through this process. The legislative process, as I can assure you, is a messy process, and I would appreciate it if you would join us in the mess, and any ideas that you have.

Before we adjourn I do want to announce that on April 6, the Subcommittee intends to hold a hearing regarding our continuing efforts to address potential problems and solutions associated with the Federal workforce.

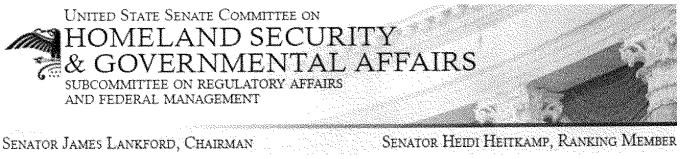
This concludes today's hearing. I do, again, want to thank your witnesses for being here today. I appreciate knowing your work. We did not get to even 10 percent of what you each submitted in your written work as well, and I do bemoan that, but we are out of time.

The hearing record will remain open for 15 days until the close of business on March 24, for the submission of statements and questions for the record.

I thank all of you again. This hearing is adjourned.

[Whereupon, at 11:59 a.m., the Subcommittee was adjourned.]

APPENDIX



Opening Statement

Hearing before the Regulatory Affairs

And Federal Management Subcommittee,

Thursday March 9th at 10:00 AM

"Agency Use of Science in the Rulemaking Process: Proposals for Improving Transparency and Accountability."

Good morning and welcome to today's Subcommittee hearing entitled "Agency Use of Science in the Rulemaking Process: Proposals for Improving Transparency and Accountability."

Over two years ago, this Subcommittee began an in-depth review of the rulemaking process, tackling subjects such as retrospective review, agency use of guidance and issues surrounding small business concerns when it comes to improving regulatory outcomes.

This morning we continue our regulatory work by examining how agencies use scientific information to inform their regulatory decision-making.

The American people should be confident that when agencies regulate they are relying on up to date, accurate, and unbiased information.

To put it simply, agencies should rely on the best available information and make decisions based on the weight of that information.

When determining whether scientific information is the best available, agencies should consider things like whether the information has been peer-reviewed by an independent third-party; whether conclusions are verifiable and reproducible; whether the information's use is consistent with its intended purpose; and whether the data is transparent and publically available.

This is not a new idea. Presidents from both parties have stressed the importance of relying on sound science to inform regulatory decisions.

Executive Order 12866, which has been in place since 1993 and endorsed by every president since, directs agencies to "base decisions on the best reasonably obtainable" scientific and technical information.

Eight years ago, President Obama went even further by issuing a memorandum to agency heads guaranteeing scientific integrity by following a list of principles that included consideration of well-established scientific processes and urging transparency to the public.

And in 2011, President Obama issued Executive Order 13563 where he directed each agency to "ensure the objectivity of any scientific and technical information" used to support regulatory actions.

Yet, despite these clear directives, agencies continue to use questionable science to support their regulatory decisions.

For example, in 2015 when the EPA proposed a ban on chlorpyrifos (chlor-pier-i-fos), an insecticide that farmers have been using successfully for decades, the agency based the regulation on a study that was discredited by their own Scientific Advisory Panel and the USDA.

I understand agencies often face difficult choices and not all studies come to the same conclusion, but it is very concerning when agencies are not open about why they choose to use a study with such significant criticism.

When agencies hide information from both Congress and the American people it is our job to question their motives and methods.

Transparency is not an unreasonable request. In fact it will go a long way in forcing better regulations and heading off lawsuits.

When agencies issue regulations that place legally binding requirements on the American people, the data the agency uses should be publically available for independent third-party review.

When many of the most costly Clean Air Act regulations are based on a single Harvard study, the EPA should not be able to hide behind the excuse that they can't release the study because they don't own it, Harvard does, despite the fact that Harvard receives well over a half of a billion dollars in federal awards.

Examples like these call into question whether agencies are actually using the best information available to them when they make regulatory decisions.

Each administration has their own priorities, but the principles supporting regulatory decisions should remain constant regardless of who occupies the White House.

If past administrations' attempts to encourage agencies to base their regulatory decisions on transparent sound science have failed, Congress should consider establishing new legal requirements.

I look forward to discussing steps Congress can take to implement these basic and fundamental requirements that have been endorsed by both Democrat and Republican administrations for decades.

With that, I recognize Ranking Member Heitkamp for her opening remarks.

U.S. Senate Committee on Homeland Security and Governmental Affairs
Subcommittee on Regulatory Affairs and Federal Management

Opening Statement of Ranking Member Heidi Heitkamp
(As prepared for delivery)

Hearing on *Agency Use of Science in the Rulemaking Process: Proposals for Improving Transparency and Accountability*

Thursday, March 9, 2017

Thank you Mr. Chairman. Today's hearing focuses on a vitally important subject.

Science is an indispensable tool for policy makers. It's fair and proper use allows us to make informed decisions based upon the weight of evidence. Science is also a key driver of technological and economic innovation. Science can create new industries and new jobs. Science can change the way we live our lives. Science also needs to be part of our nation's regulatory process.

Science, in its many varied forms, can play an important role in giving Congress, the Administration and the federal agencies important information that can help inform policy decisions. For this reason, it is critically important that our nation seeks to uphold the highest standards of scientific integrity. In the rulemaking space, a big part of that is improving transparency and accountability. It's not enough for agencies to say "trust us." They must be able to demonstrate that a decision affecting tens or hundreds of millions of Americans is fully reasoned.

Today, I hope to hear some strong ideas on how to increase transparency and accountability in a manner that is consistent with the public interest. The public should have access to data and information but we also need to include common-sense protections. No one wants personal information shared in a regulatory docket, and agencies may need access to legitimately proprietary information from businesses to make the best regulatory decision possible.

What is clear is that there is a balance to be struck. Accessibility and transparency need to be at the forefront of any discussion about regulatory reform and improving the regulatory process. However, we also have to understand that the term "science" encompasses a vast array or information and methodology in a wide variety of disciplines. It may not be possible to settle on and determine a single methodology to achieve scientific results that works across the entire federal enterprise.

I want to submit for the record a statement from Harold P. Wimmer, National President and CEO, of the American Lung Association, outlining principles to guide the use of science in federal policy development. I look forward to hearing the testimony of our witnesses and any suggestions they have to promote reasonable and balanced steps that advance our mutual objectives.

THE GEORGE WASHINGTON UNIVERSITY

WASHINGTON, DC

Prepared Statement of Susan E. Dudley

Director, GW Regulatory Studies Center
Distinguished Professor of Practice,
Trachtenberg School of Public Policy and Public Administration

Hearing on

Agency Use of Science in the Rulemaking Process: Proposals for Improving Transparency and Accountability

Homeland Security and Governmental Affairs
Subcommittee on Regulatory Affairs

United States Senate

March 9, 2017

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Agency Use of Science in the Rulemaking Process: Proposals for Improving Transparency and Accountability

Prepared Statement of Susan E. Dudley March 9, 2017

Thank you Chairman Lankford, Ranking Member Heitkamp, and Members of the Subcommittee for inviting me to share my thoughts as you consider improving the transparency and accountability of science in the rulemaking process. I am Director of the George Washington University Regulatory Studies Center, and Distinguished Professor of Practice in the Trachtenberg School of Public Policy and Public Administration.[1] From April 2007 to January 2009, I oversaw federal executive branch regulations as Administrator of the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB). I have studied regulations and their effects for more than three decades, from perspectives in government (as both a career civil servant and political appointee), the academy, and consulting.

1. The Importance of Transparency and Accountability in Regulatory Science

Effective regulatory policy that focuses resources on addressing real threats to public health and the environment depends on reliable scientific information and transparent policy choices. Unfortunately, such regulations are often the subject of heated debate, involving accusations of "politicized science."

Problems arise when political decision-makers attempt to distort what scientific studies conclude, but also when scientists and others attempt to exert influence on policy decisions by selectively presenting, or even distorting, scientific findings While there is extensive media coverage of the former, the examination of how science may be politicized *inside* federal regulatory decision-making processes has been largely limited to academia and the scientific community.

As the Subcommittee considers proposals for improving transparency and accountability in agencies' use of science in the rulemaking process, it should recognize two types of politicized science that can infect policymaking within regulatory agencies. The first is when scientists, intentionally or unintentionally, insert, but do not disclose, their own policy preferences in the scientific advice they provide government decision-makers. Such "hidden policy judgments"

[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.

lead to what has been called "advocacy science"[2] or "normative science."[3] The second is when scientists and/or policymakers conflate scientific information and nonscientific judgments to make a policy choice, but then present that decision as being solely based on science.

It is this tendency to "camouflag[e] controversial policy decisions as science" that Wendy Wagner called a "science charade"[4] and it can be particularly pernicious. For instance, a 2009 Bipartisan Policy Center (BPC) 2009 report, *Improving the Use of Science in Regulatory Policy*, concluded that "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."[5] Both of these problems, hidden policy judgments and the science charade, can be the result of officials falling prey to the "is-ought fallacy": incorrectly mixing up positive information about what "is" with normative advice about what "ought to be."

Institutional arrangements in the regulatory development process tend to aggravate both hidden policy judgments and science charades. They threaten the credibility of the scientific process and harm regulatory policy. Many of those involved in regulatory decisions have incentives to hide policy preferences, such as how to deal with the uncertainty in assessments of risk, and to dismiss and denigrate dissenting views. Key policy choices, disguised as science, too often rest with technical staff; meanwhile, policy makers charged with making hard policy decisions are able to avoid responsibility by claiming that their hands were tied by "the science."

2. Risk Assessment and Risk Management

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 obtain under different scenarios, it is not determinative for the normative decisions regarding what *ought to be*.[6] Along these lines, in 1983 the National Research Council (NRC) of the National Academy of Sciences presented a framework for making regulatory decisions regarding health, safety, and environmental risks that separated decisions into two conceptual phases: risk assessment and risk management.[7]

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[2] See, for example, Jason Scott Johnston, ed. *Institutions and Incentives in Regulatory Science*. Lexington Books (2012)

[3] Lackey, Robert T. "Normative Science." *Terra Magazine*. Oregon State University. 2013;8(2).

[4] Wagner, Wendy E. The Science Charade in Toxic Risk Regulation. Columbia Law Review. 1995 Nov;95(7): 1614; 29.

[5] Bipartisan Policy Center. Improving the Use of Science in Regulatory Policy. Washington (DC): Bipartisan Policy Center; 2009;10. Available at: http://www.bipartisanpolicy.org/sites/default/files/BPC%20Science%20Report%20fnl.pdf "BPC"

[6] See John Neville Keynes, *The Scope and Method of Political Economy*, Fourth Edition., Batoche Books: Kitchener, Ontario (1999), p. 22.

[7] National Research Council and the Committee on the Institutional Means for Assessment of Risks to Public Health. Risk Assessment in the Federal Government: Managing the Process. 1983. Washington D.C.: National Academies Press, p. 3. This document is also commonly known as the "Red Book."

The risk assessment phase provides science-based information regarding what we know about a risk (positive information regarding *what is*). While risk assessment is a necessary input for deciding how the government should regulate a risk, it is rarely sufficient. A second phase, risk management, is necessary for determining what *ought to be*. Sound policy decisions regarding risk management typically need to consider a host of non-scientific factors such as economic feasibility, legal constraints, ethical considerations, and the existence of other public policies that may address, or exacerbate, the risk, to name just a few.

Unfortunately, in practice there is not a clear distinction between scientific and policy decisions in the regulatory process. First, when it comes to risk assessment, scientists will never have complete information to predict outcomes with certainty, so analysts rely on what the NRC called "risk assessment policy" – assumptions, judgments, and rules of thumb – to guide the use of scientific information in analyses that inform policy in the face of uncertainty.[8] "Risk assessment policy" includes various judgments, including which science is considered, how individual studies are weighed and combined, when competing theories are considered appropriately supported for inclusion, which models to use, and in general, what to do in the face of scientific uncertainty. It also guides the way in which risks are characterized and communicated.[9] In other words, the risk assessment phase itself embeds judgments necessary to produce a result that scientists can give to policymakers; and these judgments, intentionally or not, can bias the ultimate advice provided to decision-makers and the public.

Policymakers and the public are often unaware of the influence of these risk assessment policy choices or the existence of alternative choices that are equally plausible. Instead, assessments often generate precise-sounding predictions that hide not only considerable uncertainty about the actual risk, but the reliance on biased inferences and assumptions for handling that uncertainty.[10] While some judgment is necessary to translate scientific evidence into risk assessments, current risk assessment policies are not transparent, and lead to distortions in risk estimates and false precision in the presentation of scientific information.[11] As former EPA scientist Robert Lackey observed "[t]oo often, scientific information presented to the public and decision-makers is

[8] National Research Council and the Committee on the Institutional Means for Assessment of Risks to Public Health. Risk Assessment in the Federal Government: Managing the Process. 1983. Washington D.C.: National Academies Press, p. 3.

[9] Dudley, SE & Gray, GM. "Improving the Use of Science to Inform Environmental Regulation," in *Institutions and Incentives in Regulatory Science,* Lexington Books, Jason Johnston ed. (2012)

[10] For example, EPA's "Risk Assessment Principles and Practices" document states: "[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. This policy position prompts risk assessments to take a more 'protective' stance given the underlying uncertainty with the risk estimates generated." (USEPA 2004, 13-14)

[11] Gray, G. & Cohen, J. "Rethink Chemical Risk Assessment." *Nature*. 2012 Sep; 489. P. 27.:"the problem is the EPA's use of assumptions that it claims are 'public health protective,' which err on the side of overstating risk when data are lacking.... Such inflated risk estimates can lead to overly stringent regulations and can scramble agency priorities because the degree of precaution differs across chemicals."

infused with hidden policy preferences,"[12] a practice he calls "normative science." These hidden policy judgments obscure the boundary between science and policy, and contribute to the politicization of science through biased science advice.

Presentations that are not transparent can mask normative science. For example, in its 2011 evaluation of EPA's Integrated Risk Information System (IRIS) assessment for formaldehyde, the National Academy of Sciences raised concerns about recurring "problems with clarity and transparency of the methods":

> In general, the committee found that the draft was not prepared in a consistent fashion; it lacks clear links to an underlying conceptual framework; and it does not contain sufficient documentation on methods and criteria for identifying evidence from epidemiologic and experimental studies, for critically evaluating individual studies, for assessing the weight of evidence, and for selecting studies for derivation of the [reference dose] RfCs and unit risk estimates.[13]

While embedded policy judgments raise concerns of hidden bias in the *risk assessment* phase of a rulemaking, policy judgments couched as "science" can raise similar problems in the *risk management* phase.

While there should be a clear distinction in the minds of scientists and policymakers between describing what "is" and deciding what "ought to be," the two are sometimes unintentionally, or intentionally, conflated when the ultimate policy decision is presented as dictated solely by "the science." We adopt the phrase "science charade"[14] to describe the camouflaging of controversial policy decisions as science.

Scientists and/or policymakers create a science charade by describing a policy decision in purely scientific (or scientific sounding) terms without revealing the trans-science[15] and policy factors that played a role in the decision. Scientists can unwittingly impose, or intentionally foist, science charades on decisionmakers by hijacking risk management decisions. Policymakers can create science charades on their own, or scientists and policymakers may cooperate in disguising value-laden decisions as the necessary result of "the best science." Regardless, the science

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[12] Lackey 2013.

[13] Committee to Review EPA's Draft IRIS Assessment of Formaldehyde; National Research Council. *Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde*. Washington (DC): National Academy of Sciences; 2011: 4. Available at: http://www.nap.edu/catalog.php?record_id=13142

[14] See Wagner 1995.

[15] Alvin M. Weinberg. "Science and Trans-Science." *Science* 177.4045 (1972): 211. Print. "I propose the term trans-scientific for these questions since, though they are, epistemologically speaking, questions of fact and can be stated in the language of science, they are unanswerable by science; they transcend science... Scientists have no monopoly on wisdom where this kind of trans-science is involved...."

charade results in similar harms as hidden policy judgments in risk assessments: the public is cheated of sound and open policy making and the integrity of science advice is weakened.

Both hidden policy judgments in risk assessments and science charades result from incorrectly mixing up positive information about what "is" with normative advice about what "ought to be." These errors are examples of the "is-ought fallacy."[16] Scientists and policymakers may intentionally invoke the is-ought fallacy, although for different reasons. Scientists may wish to influence policymakers by subtly absorbing nonscientific assumptions in their risk assessments or in descriptions of what "is" so that it appears there is no better risk management alternative than the one they prefer. Likewise, decisionmakers, such as political appointees, who may fear criticism of a particular decision can muddle descriptions of what "is" with assumptions regarding what "ought to be" in the risk management phase of rulemaking and claim that "science" dictated the outcome. In both cases, the fallacy allows scientists and/or policymakers to create a science charade by disguising a policy decision in a lab coat.

3. The harms of politicized science and the example of NAAQS

In a forthcoming article, Marcus Peacock and I use the process by which EPA sets National Ambient Air Quality Standards (NAAQS) for "criteria pollutants"[17] under the Clean Air Act to illustrate some of the perverse incentives involved in developing regulations, which can encourage biased science advice and a science charade. We found the NAAQS process particularly worth examining because, on the one hand it is held up by some as an ideal by which all science-based rulemaking should be developed,[18] but on the other, NAAQS decisions are among the most controversial of EPA policies. Each of the last three presidents has taken the highly unusual step of publicly and personally intervening in EPA's regulatory decisions.[19]

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[16] Also called the "naturalistic fallacy," the "positive-normative fallacy," Hume's Law and Hume's Guillotine.

[17] The Clean Air Act, 42 U.S.C. § 7408 (a)(1) identifies six "criteria pollutants": particulate matter, ground-level ozone, carbon monoxide, sulfur oxides, nitrogen oxides, and lead. Available at: http://www.gpo.gov/fdsys/pkg/USCODE-2008-title42/pdf/USCODE-2008-title42-chap85.pdf

[18] Wendy Wagner. "Science in Regulation: A Study of Agency Decision making Approaches" (referring to the NAAQS development process as "the equivalent of a five-star process for incorporating science into regulatory policy.") 2013: 29. Available at: http://acus.gov/report/science-regulation-final-report

[19] EPA's 1997 standards for ozone and fine particles were debated extensively at the cabinet level and, on issuance of the final regulations, President Clinton took the unprecedented step of writing a public memorandum to the EPA Administrator on "Implementation of Revised Air Quality Standards for Ozone and Particulate Matter," to "ensure that the new standards are implemented in a common sense, cost-effective manner." Available at: http://www.gpo.gov/fdsys/pkg/WCPD-1997-07-21/pdf/WCPD-1997-07-21-Pg1080.pdf) (See Arthur Fraas, "Observations on OIRA's Policies and Procedures," Administrative Law Review, Vol. 63:2011 at 81-85 for an insider's account of the 1997 deliberations.) In 2008, EPA again faced objections from other agencies, as well as from state and local governments, when it proposed to revise the ozone standard. President George W. Bush was called in to settle the dispute, following the rarely used section 7 of E.O. 12866 regarding the resolution of conflicts. He decided the dispute over the appropriate form of the welfare standard by directing EPA Administrator Stephen Johnson to set it at a level identical to the primary standard. Available at: http://www.reginfo.gov/public/postreview/Steve_Johnson_Letter_on_NAAQs_final_3-13-08_2.pdf In 2011, the President intervened again. EPA was poised to revise the ozone standard amid strong objections from other parts of

The Clean Air Act directs EPA to set NAAQS to "protect public health" with an "adequate margin of safety," but falls prey to the is-ought fallacy and encourages the science charade by restricting the agency from openly considering relevant nonscientific factors. Combined with tight deadlines, the statutory language permits Congress to take credit for laudable public goals, while blaming the executive branch's execution for any undesirable outcomes. 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 hiding policy judgments and developing scientific-sounding explanations to justify one standard over another, and public interveners vigorously defend alternative standards based on their own interpretation of the "science."

Scientists argue for the primacy of their data, analysts have an incentive to downplay rather than reveal uncertainties regarding their predictions or the implications of key risk assessment policy choices, and decision makers point to science as either requiring a new standard or as determining that existing standards are adequate.

This has evolved into an adversarial process, characterized by harsh rhetoric in which each party claims the science supports its preferred policy outcome and questions opponents' credibility and motives, rather than a constructive discussion regarding appropriate data, assumptions and normative decisions. The real reasons for selecting a particular standard may not even be discussed. This harms the credibility of science advice and results in poorer decision making.

4. Recommendations

In thinking about reforms to improve how science is used in developing regulations, clarifying which aspects of the decision are matters of science and which are matters of policy is essential to avoid both hidden policy judgments and the science charade. When people condemn the "politicization" of science,[20] the problem may really be that we ask too much of science in addressing policy problems.

As the BPC recommended, a focus of reform should be on devising regulatory processes that, "in as many situations as possible, ... help clarify for both officials and the general public which aspects of disputes are truly about scientific results and which concern policy."[21] This would not only help address the is-ought fallacy, but also the problem of hidden policy judgments, in which the effect of risk assessment policy judgments on estimates of outcomes are not acknowledged.

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the government and the regulated community, when President Obama took the unusual step of "request[ing] that Administrator Lisa Jackson withdraw the draft ozone NAAQS" from interagency review. Available at: http://www.whitehouse.gov/the-press-office/2011/09/02/statement-president-ozone-national-ambient-air-quality-standards. This is the only time during President Obama's administration that the White House returned a regulation to an agency.

[20] Mooney, C. The Republican War on Science. New York: Basic Books; 2006.

[21] Bipartisan Policy Center, 2009:4.

"This transparency would both help force values debates into the open and could limit spurious claims about, and attacks on, science."[22]

In our forthcoming article, Marcus Peacock and I offer a set of recommendations that attempt to alter the incentives of the parties to the rulemaking process to 1) address behavior contributing to the is-ought fallacy, 2) address the problem of hidden policy judgments, and 3) improve incentives generally. The following eight suggestions are based on that article.

1. **Recognize that "science" is a positive discipline that can inform, but not decide, appropriate policy.**

In drafting authorizing legislation, Congress should not delegate decisions to agencies on the pretense that science alone can make the normative determination of what policy ought to be. Some statutes directed at health, safety, and environmental risks have facilitated more rational regulatory policy than others by recognizing that risk management requires normative judgments that consider tradeoffs. For example, the Safe Drinking Water Act requires EPA to consider the costs as well as the benefits of requiring local water authorities to install controls for specific substances. Perhaps that is one reason why the debates over drinking water standards are generally less acrimonious than debates over ambient air quality standards. Since the statute allows explicit consideration of tradeoffs when setting standards, the full burden of decision-making is not vested in the risk assessment. As a result, policy makers and interested parties may have less incentive to embed policy preferences in the risk assessment portion of the analysis, because they can debate them openly and transparently in the risk management discussion.[23]

2. **Legislators and policymakers must clarify the appropriate role for scientific advisors.**

The engagement of scientific advisory panels can provide a necessary and valuable source of information and peer review for agency science, but greater efforts should be made to restrict their advice to matters of science, and not ask them to recommend regulatory policies. When asked to advise on policy choices, it is impossible for members not to be tempted to wrap their policy views in a lab coat and present them as scientific recommendations.[24] As reports from both the BPC and the Keystone Center[25] emphasized, the questions posed to such panels "should

[22] Bipartisan Policy Center, 2009:5.
[23] Dudley & Gray, 2012.
[24] See, for instance, the recommendation of former CASAC member Morton Lippman regarding changing the Clean Air Act. Lippman noted "CASAC's role must be limited to highlighting the issues at the science-policy interface and the scientific knowledge that informs these issues." Dr. Morton Lippman. "Comments on the NAAQS Review Process." 2006, at A-22. http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/Vanessa%20Memo_03-16-06/$File/sabso-casac_memo_and_comments.pdf
[25] The Keystone Center. Research Integrity Roundtable. Improving the Use of Science in Regulatory Decision Making: Dealing with Conflict of Interest and Bias in Scientific Advisory Panels, and Improving Systematic Scientific Reviews. Washington (DC): The Keystone Center; 2012. Available at:

be clearly articulated, and 'explicitly differentiate, to the extent possible, between questions that involve scientific judgments and questions that involve judgments about economics, ethics, and other matters of policy.'"[26] Experts with formal training and experience in policy analysis, economics, law, and other disciplines are much better equipped to provide advice on these latter questions.

3. **Establish procedures and incentives to make more transparent the effect different credible risk assessment inputs and assumptions have on the range of plausible outcomes.**

Risk assessments necessarily involves assumptions and judgments as well as pure scientific inputs, yet they often generate precise-sounding predictions that hide not only considerable uncertainty about the actual risk, but hidden policy judgements.[27] One way to make risk assessment policy choices more transparent to decisionmakers and the public would be for agency scientists to calculate and present multiple risk estimates based on a variety of scientifically plausible data sets, endpoints, models, *etc.*,[28] rather than embedding multiple risk assessment policy choices in a single assessment.[29] Greater transparency regarding the assumptions and policy rationales for choosing one set of assumptions or models over another would encourage more openness and constructive discussion about science and policy, improving the ultimate policy decision and probably engendering greater acceptance of that policy choice.[30]

4. **Institutionalize reforms that encourage greater feedback and challenge of risk assessment practices and policy choices.**

The scientific method depends on falsifiable hypotheses, data gathering, replication, dissent, and challenge, to ensure objective analysis to minimize bias in the interpretation of results. Institutional reforms that intentionally engage, rather than avoid, competing views, could go a long way to improve the clarity of the risk assessment process and the decisions that depend on scientific input. Successful reforms might involve pre-rulemaking disclosure of risk assessment information to engage broad public comment on the proper choice of studies, models,

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https://www.keystone.org/images/keystone-center/spp documents/Health/Research%20Integrity%20Rountable%20Report.pdf

[26] The Keystone Center, 2012: 8. (Internal citation to BPC at 5.)

[27] Dudley et al, "Consumers Guide to Regulatory Impact Analysis: Ten Tips for Being an Informed Policymaker," GW Regulatory Studies Center Working Paper, February 2, 2017. Available at: https://regulatorystudies.columbian.gwu.edu/consumer%E2%80%99s-guide-regulatory-impact-analysis

[28] Dudley & Gray 2012

[29] Lackey, 2013.

[30] Dudley & Gray, 2012.

assumptions, etc. long before any policy decisions are framed, and "positions" established.[31] Advanced notices of proposed rulemaking could be used effectively to gather such input.[32]

5. Scientific advisory panels should be required to represent a diversity of perspectives, disciplines, expertise, and experience.

The 2012 Keystone Group report offers a series of recommendations on "the composition of committees that are empaneled to review the science behind a regulatory decision."[33] Acknowledging the importance of choosing panelists that "have the knowledge, training, and experience needed to address the charge to the panel,"[34] it admonished agencies "to recognize that all potential panelists will have conscious and unconscious biases," and said that "the panel selection process requires review of the disclosed information and a judgment as to the ability of each prospective panelist to participate in open discussion and to consider other perspectives."[35]

6. Encourage feedback through retrospective review of regulatory outcomes.

Regulatory programs are rarely subjected to rigorous evaluation and feedback. Most regulatory analyses rely on models and assumptions to make predictions about the risk reduction benefits that will accrue from a specific intervention. Institutionalizing a requirement to evaluate whether the predicted effects of the regulation were realized would provide an incentive to improve the use of science for predicting the benefits of interventions. Agencies should be required to include in proposed regulations a framework for empirical testing of assumptions and hypothesized outcomes.[36] To incentivize more robust evaluation, agencies could be required to test the validity of risk-reduction predictions before commencing new regulation that relies on models.

7. Regulations should be designed to facilitate natural experimentation and learning.

Designing regulations from the outset in ways that allow variation in compliance is essential if agencies are to go beyond observing mere associations and gather data necessary to test hypotheses of the relationship between regulatory actions, hazards, and risks. Quasi-experiments,

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[31] Balla, Steven J. and Dudley, Susan E. "Stakeholder Participation and Regulatory Policymaking in the United States." A report prepared for the *Organisation for Economic Co-operation and Development*. 2014. http://regulatorystudies.columbian.gwu.edu/sites/regulatorystudies.columbian.gwu.edu/files/downloads/Balla-Dudley-US-Stakeholder-Reg-Process-11-2014.pdf

[32] See, for example, S. 1820, "Early Participation in Rulemaking Act of 2015." https://www.congress.gov/bill/114th-congress/senate-bill/1820/text

[33] Keystone, 2012:4.

[34] Keystone, 2012:14

[35] Keystone, 2012:15

[36] For example, see S. 1817, "Smarter Regs Act of 2015," https://www.congress.gov/bill/114th-congress/senate-bill/1817/text

relying on differences in treatments (such as differences in attainment status with NAAQS) can inform risk assessments going forward.[37]

8. Greater weight should be placed on scientific studies that were subject to peer review and whose results are reproducible.

Peer review is often considered a fundamental component of the scientific process and scientific publishing is focusing more on the sharing of data and experimental transparency.[38] Disclosure of underlying data and computer code has become standard among the more prestigious scientific and technical journals, which allow for data sharing agreements when individually-identifiable information prevents public disclosure.[39] These disclosure policies appear to improve the reproducibility of the results of published papers.[40]

* * *

No one is immune to the temptation to spin science to advance a pre-determined policy goal. However, masquerading policy preferences as "science" can be extremely harmful. As former Assistant Administrator of the U.S. Environmental Protection Agency, Milton Russell, has noted, while government scientists need to be protected from "influence over what they *find and report,*" "policy-makers must be protected from policy analysts or scientists telling them what they should *decide*, but open to information about what the consequences of alternative decisions are likely to be."[41]

Current regulatory institutions and procedures tend to aggravate two contributors to the politicization of science: "hidden policy judgments" (not acknowledging the policy judgments inherent in risk assessment) and "science charades" (camouflaging policy decisions as science). Both of these problems threaten the credibility of the scientific process and harm regulatory policy.

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[37] For an illustration of this method applied to the competitive effects of NAAQS, see Greenstone, M., List J.A., Syverson, C. "The Effects of Environmental Regulation on the Competitiveness of U.S. Manufacturing." MIT Center for Energy and Environmental Policy Research working paper. CEEPR WP 2012-013; 2012.
[38] Joel Achenbach, "The new scientific revolution: Reproducibility at last." Washington Post. January 27, 2015.
[39] Dudley et al, 2017, Tip 6.
[40] Randall Lutter and David Zorn. 2016. "Reinforcing Reproducibility: What Role for the Federal Government?" *Regulation* Winter 2015-16: 15-16.
https://object.cato.org/sites/cato.org/files/serials/files/regulation/2015/12/regulation-v38n4-8_4.pdf#page=10.
[41] Milton Russell, "Lessons from NAPAP," *Ecological Applications*, 2(2), 1992, p. 108.

Written Testimony of Andrew A. Rosenberg, Ph.D.
U.S. Senate Subcommittee on Regulatory Affairs and Federal Management
"Agency Use of Science in the Rulemaking Process: Proposals for Improving Transparency and Accountability"
March 9, 2017

Chairman Lankford, Ranking Member Heitkamp, and Members of the Senate Homeland Security and Governmental Affairs Subcommittee on Regulatory Affairs and Federal Management:

Thank you for the opportunity to testify today to discuss the important role that science plays in the rulemaking process. I am Dr. Andrew Rosenberg, Director of the Center for Science and Democracy at the Union of Concerned Scientists. I have more than 25 years of experience in government service, academia, private sector consulting, and non-profit leadership, have authored over 100 peer reviewed papers, as well as numerous national and international scientific reports on fisheries and ocean science policy, and on the intersection between science and policymaking.

Within the U.S. government, I have served as a scientist and regulator under both Democratic and Republican administrations, including as the Deputy Director of National Oceanic and Atmospheric Administration's (NOAA) National Marine Fisheries Service. I have also taught in academia for more than ten years, and was the former Dean of Life Sciences and Agriculture at the University of New Hampshire. Since 2012, I have directed the Center for Science and Democracy at the Union of Concerned Scientists.

The Union of Concerned Scientists puts rigorous science into action for a healthier planet and a safer world. Our staff includes scientists, engineers, economists, and analysts working to address some of today's most pressing problems. Backed by a network of more than a half-million supporters and some 20,000 scientists and technical experts across the country who are a part of our Science Network, we believe that scientific analysis should guide government policies. For nearly 50 years, UCS has championed and continues to advocate for the need to base our governmental decisions on the best scientific and technical information available.

The Center for Science and Democracy at the Union of Concerned Scientists works to strengthen the role science plays in policy and community decisions. We work to ensure that policymakers and the public have access to the independent scientific information needed to make informed decisions about public health, safety, and the environment. Furthermore, we lay out a positive vision of how independent science and scientists can be made more impervious to political influence, such as implementing strong scientific integrity policies and maintaining strong conflict of interest standards at federal agencies and federal scientific advisory boards.

Science in the Policy-making Process

Science plays a critical role in the policy decisions made by the federal government that impact Americans' health and safety, from ensuring that drugs are proven to be safe and effective, to keeping our food free of disease, to keeping our drinking water clean, to assuring safe working conditions for workers, and protecting our natural resources. While these decisions are not made based on scientific and technical assessments alone, technical input is integral to the regulatory process. Science provides government agencies and the public the ability to assess public health, safety, and environmental threats, evaluate the impacts of possible policy responses, and make informed decisions to protect the public interest. Science allows us to monitor ongoing results and emerging concerns on a wide range of issues from rapidly proliferating infectious diseases to dangerous and pervasive air pollutants. Using science to inform policy decisions and involving the public throughout the decision-making process is critical for public trust in the operations of the government and upholds our democratic principles. My experience as a scientist and manager has affirmed that good governmental decisions require the best scientific and technical information available, unfettered by political, financial, or ideological influence.

The scientific process consists of continuous and incremental discoveries in multiple fields of study accumulating a weight of evidence and building toward broad acceptance of facts within the scientific community.

Weight of the evidence refers to the cumulative body of scientific research and analysis that pertains to a particular subject. "Weight" refers not only to the number of studies but also their importance, robustness, and credibility in drawing scientific inference. Credibility relates to the design of the study, analytical methods and methods of inference, as well as the provenance of the work with regard to potential conflicts of interest, peer reviews conducted, and comparison to other relevant studies. These elements are a key part of the scientific process.

A valid and credible scientific process consists of a rigorous examination of ideas, review, and critique by technically qualified peers, open exchange of ideas among colleagues, and protection against manipulation of results by vested interests or retaliation for one's scientific findings. Freedom to participate in the scientific process ensures that technological innovations and attendant benefits to society are supported and protected.

Some environmental statutes require that agencies make decisions based solely on the best available science while others require science to be used in certain discrete parts of the regulatory decision. For example, the Clean Air Act requires National Ambient Air Quality Standards be set using the best available science on the link between air pollutants and health effects, but allows for other considerations including economic factors when implementing the standards. It is, of course, the agency's responsibility, with input from qualified scientific

advisers, to abide by their statutory obligations when conducting rulemaking and to consider the weight of the evidence as required by law.

I serve as a regular reviewer for several scientific journals, as a member of two editorial boards, and as an independent reviewer for national and international reports (e.g. from governments or United Nations bodies). In this capacity, I consider the framing of a study, the methods, the results, and the researcher's interpretation in light of my knowledge of the field and relevant scientific literature. I may not agree with all inferences drawn by the researchers in the discussion, but if the aforementioned components are well executed, then a paper merits publication in my view. Every paper is subtly different and should be judged by experts in the field on its merits. This is generally true of the science used in the regulatory process as well.

Here, the question arises, what is best available science? And what is independent science? In my view, and the view of most of the scientific community, best available science is research that is conducted in accordance with well-established scientific practices, including a well-designed investigation, logical and statistically rigorous analysis, clear documentation of data collection and analytical methods, as well as results free from external influences that may support a particular policy position, and careful peer review. I strongly believe that these generally accepted standards cannot be clearly legislated without undermining innovation and accounting for the broad array of scientific methods.

Science is an ever-evolving process. Legislating what is considered to be the "best available" removes the process of science from scientists and puts it in the hands of legislators and the courts. As former congressman and current chief executive officer of the American Association for the Advancement of Science (AAAS) Rush Holt told the House Committee on Science, Space, and Technology earlier this year:

> "Legislation removing concepts like reproducibility and independent analysis from the hands of scientists and into a legislative chamber or a court room would truly have a chilling effect on the scientific process and reduce the benefits that science could bring to society. Seeking to influence the scientific process has no place in how a government or other entity should conduct science."[1]

Furthermore, if one were to legislate what should be legally considered "best available science," it would prevent the innovation and flexibility that is inherent in the scientific process. This ability to learn is essential for agencies as they address new discoveries like autonomous vehicles and advancements in nanotechnology. As we learn more, science continues to evolve. New research leads to a better understanding of complex challenges that we face today, allowing experts to make appropriate determinations, sometimes erring on the side of caution when faced with uncertainty or limited data to best protect the public.

When I was working as a lead regulator in the Northeast, research findings from federal, state, and academic scientists on New England and mid-Atlantic fisheries indicated an overexploitation of the resource. While of course there was uncertainty in the exact status of fishery resources, the risk of not taking action with regard to public trust resources outweighed the uncertainty. The fishing industry and other members of the public had ample opportunity to present their views and evidence. Opinions of those in the industry were very influential in the process, alongside the science. But the scientific evidence that accumulated over many years ultimately led us to take measures to curb overfishing with the result that some of the fish stocks recovered and now support vibrant fisheries.

While it is important to document where the uncertainty lies, it is also necessary to act once the weight of evidence is compelling enough to justify reasonable, evidence-based policy solutions. The weight of scientific evidence cannot be tilted with just one study. A poorly conducted study, unduly influenced by a vested interest, should not be equally considered along with the multitude of peer reviewed and well-executed studies.

As I noted, peer review is a critically important quality control mechanism if it is well conducted. But, make no mistake, it is possible to misuse the process. A case in point is that tobacco company, Phillip Morris, used a phony peer review process to falsify research in an effort to stop or circumvent regulations around light cigarettes and their relationship to nicotine addiction, tar consumption, and disease, including cancer. The company hired scientists from industry-friendly consulting firms to publish a study in Regulatory Toxicology and Pharmacology, which had a record of publishing research paid for by industry.[2] It used this published study which underwent conflicted peer review, to dispute the scientific consensus on the harms of light cigarettes and the findings of the Surgeon General, the National Academy of Sciences, the National Cancer Institute, and the American Cancer Society, whose research found that lung cancer mortality rates among smokers increased after light cigarettes began dominating sales.[3] In this case, the degree to which the tobacco industry paid for and influenced the research demonstrated a clear conflict of interest, limiting the credibility of the study. The telling analysis of this study's diminished credibility was accomplished not by reviewing raw data, but through an examination of the conflicts of interest and the methodology.

Public Access to Science

We are probably all in agreement that public access to the science that underlies regulatory decisions is important so that the public can fully engage in the democratic process and to ensure that the rationale for decisions is clear, even if we all don't agree with the final policy outcome. However, access to critical scientific information must be granted only while maintaining necessary confidentiality and respecting privacy concerns.

On this point, it is important to distinguish between data and science. The scientific information critical for an informed public is information on how studies are conducted, how the information is interpreted, and inferences that are drawn. This is not dissimilar to the information a peer reviewer like me considers in evaluating a study, albeit for the public in a non-technical form. I cannot think of an example of a peer reviewer requiring access to raw data in reviewing a study.

Access to underlying data may of course be important for other researchers to use in their own studies as the scientific process proceeds. I have analyzed long-term datasets that were collected by others in many studies. Access to that data must respect confidentiality provisions, intellectual property, commercial confidentiality, and of course the opportunity of the original researchers to publish their results first. Confidentiality is critical and required by research institutions, through their Institutional Review Boards, for any studies including people. For example, medical data relied upon by public health researchers and used by agencies may not be publicized because of sensitive, personal information and other legal violations. As noted above it is important to distinguish between raw, confidential data and scientific analyses that might be used by an agency in the analysis of public health and safety protections.

Legislation like the Honest and Open New EPA Science Treatment Act of 2017 is misleading and fails to adequately address this distinction. It would effectively disallow agencies from using protected raw data and thereby restrict the government's ability to meet its statutory obligations based on science to protect public health and the environment. Most critical and illogically, the result would be that the public would not be protected from genuine threats to health and safety because of restrictions in data access protecting the privacy of members of the public. Further, such restrictions would increase costs and burdens to agencies, while undermining the ability for agencies to make decisions based on incredibly important research using confidential public health information. This is all to no purpose, since the raw data is not needed in order for the public to be informed about scientific information.

For example, the landmark Harvard Six Cities study published in 1993 relied upon longitudinal cohort data using individuals' medical and occupational histories as well home air quality data in order to study the association between chronic exposure to air pollution and mortality in six major U.S. cities.[4] This study was *one of many* assessments used by the Environmental Protection Agency (EPA) in determining the need for new particulate matter standards to improve health outcomes in the United States.[5] However, some elected officials have politicized this study, calling its data "hidden" and asking the EPA to provide the raw data for "independent scientific verification," despite the study having been peer reviewed and subsequently reanalyzed by independent researchers.[6] But in order for the scientific process to work, the rights and privacy of study participants must be protected and the analyses based on these data must be used by agencies using a credible scientific process. If citizens did not feel like their private health information could be protected, they would not volunteer for these types of studies that help federal and state agencies ensure the strongest public health safeguards for all Americans.

There are other reasons as well, for not allowing unlimited access to underlying data. For example, the underlying data can be proprietary in nature, whether it is being shared with federal agencies by regulated industries, other private entities, or scientists who are conducting their own research. To return to my own direct experience as a regulator, fishermen and others who work on the water are intensely protective of data about their activities. And public access to raw data is unnecessary for people to understand the scientific analyses underpinning regulations. But requiring public access to some data would potentially disadvantage some businesses.

A Framework for Independent Science in Rulemaking

A coherent, publicly credible and acceptable framework to assure that scientific advice is independent is needed as an antidote to vested interests seeking to use science to justify pre-determined policy positions for economic, political, or ideological gain. Agency rulemaking must be informed by independent scientific advice that is free from political pressure. As stated earlier, components of independent science include peer review, disclosure of potential conflicts of interest, public availability of research findings and methodology, freedom to publish research, and mitigation of scientific misconduct.

Agencies have procedures in place that facilitate best practices to advance the role of science in the rulemaking process. Twenty-four federal agencies have developed scientific integrity policies in response to a 2009 White House directive, many of which provide the protections necessary to foster a culture of scientific integrity at federal agencies.[7] There is now legislation in both the House and Senate that would enshrine the requirement that the scientific integrity policies remain in place, which I view as a positive step to protect science-informed policymaking. Further, many government agencies, including the EPA, NOAA, the U.S. Fish and Wildlife Service, the National Institutes of Health, and the Centers for Disease Control and Prevention, also have strong peer review policies that encourage rigorous and transparent scientific analysis and further safeguard the government scientific process.[8] When free from undue influence, the scientific process and its ability to inform government decisions works well, but this process can still be undermined by political interference.

Examples of political interference in the rulemaking process can include manipulating scientific or technical results, selectively editing agency scientific documents, exaggerating uncertainty while downplaying what is known, tampering with scientific procedures, intimidating, censoring or coercing scientists, suppressing scientific findings, disregarding scientific findings when legally mandated to consider them, and allowing conflicts of interest in decision-making processes.[9] Scientific integrity policies at departments and agencies help to minimize interference in the role of science in the regulatory process and create a culture of scientific integrity within the government. Engagement of the public and ensuring access to scientific information (not raw data) throughout the regulatory process also enhances the role of science in our democracy.

Agencies should use the best available scientific information in rulemaking as guided by their missions and statutory obligations. "Best available" should be used to describe the weight of evidence which only includes science developed by a credible process for ensuring independence from undue influence by vested interests. Agency scientists, supported by a commitment to a rigorous independent science, scientific integrity policies, and appropriate transparency measures, should be trusted to analyze available data and issue policies that consider and value the weight of the evidence. All Americans benefit when science is used to inform policy, and its integrity in the rulemaking process is imperative for a functional democracy and a safer, cleaner environment for all.

Mr. Chairman, Ranking Member, and members of the committee, I appreciate the opportunity to share my views and I am happy to answer any questions.

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Written Statement of
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Before the
U.S. Senate Committee on Homeland Security and Governmental Affairs
Subcommittee on Regulatory Affairs and Federal Management
Regarding a Hearing on the Agency Use of Science in the Rulemaking Process:
Proposals for Improving Transparency and Accountability

March 9, 2017

American Chemistry Council
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Summary

The American Chemistry Council (ACC)[1] appreciates this opportunity to provide testimony on Federal Agency use of science in the rulemaking process, and particularly on proposals for improving transparency and accountability.

The business of chemistry is a critical component for manufacturing safe, high quality products and 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. Similarly, they expect high quality, up to date science and relevant reliable assessment processes to underpin regulatory decisions by the Federal government.

Reliance on the highest quality, best available science is critical to ensuring public trust. Without it, consumers are at a severe disadvantage. Stakeholders can lose confidence in regulatory decision making, which in turn can lead to product de-selection that is not supported by science, unwarranted public alarm and unnecessary costs.

ACC supports actions to enhance the integration of the best available scientific knowledge and weight of the evidence methods as the foundation for regulatory decision making across Federal Agencies. We also support improving the technical quality and objectivity of Agency evaluations, particularly through enhancing the transparency of how the science is being considered, interpreted, and evaluated.

In 2002, Federal Agencies were directed to ensure the quality, objectivity, utility and integrity of information which they disseminated to the public.[2] In theory, this should have had a direct impact on improving the quality of scientific analyses that support regulatory decisions. Unfortunately, while most Agencies have committed to meeting these standards, we have seen that some of the scientific analyses that have come out of the EPA and other Federal Agencies fall short of meeting the objectivity and quality standards discussed in the government-wide Information Quality Guidelines.

[1] 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 environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a $797 billion enterprise and a key element of the nation's economy. It is the nation's largest exporter, accounting for fourteen percent of all U.S. exports. It is also one of the nation's most heavily regulated industries. Chemistry companies are among the largest investors in research and development.

[2] Pursuant to what is commonly referred to as the Information Quality Act (Sec. 515 of the Treasury and General Government Appropriations Act for FY 2001, Pub. L. No. 106-554), the Office of Management and Budget (OMB) issued government-wide Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies (2002), 67 Fed. Reg. 8452 (Feb. 22, 2002) [hereinafter Information Quality Guidelines], available at: https://georgewbush-whitehouse.archives.gov/omb/memoranda/fy2007/m07-24.pdf;

ACC's testimony today discusses some of the standards that already exist, discusses the new Lautenberg Chemical Safety Act scientific standards, and provides some suggestions for ensuring the quality of science that supports regulatory activities. We also share examples of where some Agencies' scientific evaluations continue to fall short.

I. The Need for Confidence in Science

As we are all aware from the news media, there is a large public perception that science may not inform Federal Agency decision making. Indeed even organizations like the American Association for the Advancement of Science (AAAS) have now become official partners in the planned April 22, 2017 March for Science. Dr. Rush Holt, the CEO of AAAS has stated "We see the activities collectively known as the March as a unique opportunity to communicate the importance, value and beauty of science."[3] Concerns about confidence in science, particularly to inform regulations, is not new and certainly did not begin with the 2016 elections.

In 2013, George Mason University conducted a survey to help capture the viewpoints of the scientific community on the state of regulatory risk assessment. The survey "Expert Opinion on Regulatory Risk Assessment" reached out to all members of the Society of Toxicology Risk Assessment Specialty Section, the Society for Risk Analysis Dose Response Section and the International Society for Regulatory Toxicology and Pharmacology.[4] The survey focused on how well and how frequently critical parts of a risk evaluation were conducted (e.g., was there a problem formulation, were standardized protocols used for data collection, was a weight of evidence approach used, was peer review sufficient). In general, the findings showed that there is widespread concern over the current application of these procedures and also showed concerns about the amount of attention given to scientific factors in risk management.[5]

In July 2016, almost 200 toxicologists signed "an appeal for the integrity of science in public policy."[6] This appeal urges legislators to embed the "rules of evidence" of the scientific method in statutes governing administrative policy and regulations. These scientists are concerned that precautionary regulations and policies are being presented as objective science, when in reality they are not. In another recent article, Dr. Andrew Rosenberg of the Union of Concerned Scientists stated, "When science is sidelined from policy decisions, we all lose."[7] ACC shares the concerns and recommendations of this diverse set of scientists. Too often we see scientific assessments, or even policies, that are driven by default assumptions rather than actual scientific evidence.[8]

ACC has consistently called upon the EPA to improve the design and conduct of its chemical assessments. In 2014, ACC released Principles for Improving Chemical Hazard and Risk

[3] See Science Magazine, Feb 28, 2017 article available at: http://www.sciencemag.org/news/2017/02/will-they-or-won-t-they-what-science-groups-are-saying-about-joining-march-science.
[4] The Survey and results can be found at: https://cmpa.gmu.edu/wp-content/uploads/2013/12/GMU-Study-Report.pdf.
[5] Ibid at page 2.
[6] See article available at: http://www.sciencedirect.com/science/article/pii/S0300483X16301123.
[7] See Science Magazine, Feb 17, 2017 article available at: http://science.sciencemag.org/content/355/6326/696/tab-pdf.
[8] See NIOSH Carcinogen Policy example provided in Appendix 1 of this testimony.

Assessments.[9] ACC did not invent these principles. For years, authoritative bodies, like the National Academy of Sciences (NAS), have provided similar constructive input to the EPA.[10] Appendix 1 of this testimony provides some specific examples of cases where Federal Agency evaluations have not met scientific standards.

II. Tools and Standards Exist to Improve Agency Science

Improving Federal Agency science should not be as challenging as it has been. Significant governmental and non-governmental guidance already exists. As noted below, often this guidance is not followed.

a. Information Quality Guidelines

In 2002, the Office of Management and Budget (OMB) released the Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies (Information Quality Guidelines).[11] The guidelines were then adopted by Federal Agencies and the OMB's principles were to be reflected in the agency-specific guidelines.

With regard to the analysis of risks to human health, safety and the environment, Agencies have adopted or adapted the quality principles applied by Congress to risk information used and disseminated pursuant to the Safe Drinking Water Act (SDWA) Amendments of 1996 (42 U.S.C. 300g-1(b)(3)(A) & (B)). In these amendments, Congress emphasized that EPA must use the best available scientific evidence for risk information. Since the Information Quality Guidelines directed all Agencies to adopt this standard, Agencies were directed, "to the degree that an Agency action is based on science," to use:

> (i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data).

Additionally, the 1996 SDWA amendments directed EPA "to ensure that the presentation of information [risk] effects is comprehensive, informative, and understandable." The Information Quality Guidelines adopted this language and directed all Agencies:

> [I]n a document made available to the public in support of a regulation [to] specify, to the extent practicable:[12]

[9] See ACC principles available at: https://www.americanchemistry.com/Chemical-Hazard-and-Risk-Assessments-Principles/ and further details at: https://www.americanchemistry.com/Policy/Chemical-Safety/Chemical-Assessments/Principles.pdf.

[10] See for instance chapter 7 in the 2011 NAS Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde available at: https://www.nap.edu/catalog/13142/review-of-the-environmental-protection-agencys-draft-iris-assessment-of-formaldehyde.

[11] The Information Quality Guidelines are available at: https://georgewbush-whitehouse.archives.gov/omb/memoranda/fy2007/m07-24.pdf.

[12] Bracketed language reflects changes to text for clarity.

(i) each population addressed by any estimate [of applicable risk effects];
(ii) the expected risk or central estimate of risk for the specific populations [affected];
(iii) each appropriate upper-bound or lower-bound estimate of risk;
(iv) each significant uncertainty identified in the process of the assessment of [risk] effects and the studies that would assist in resolving the uncertainty; and
(v) peer-reviewed studies known to the [agency] that support, are directly relevant to, or fail to support any estimate of [risk] effects and the methodology used to reconcile inconsistencies in the scientific data.

b. Memorandum on Updated Principles for Risk Analysis

In 2007, OMB and the Office of Science and Technology Policy (OSTP) issued a joint memorandum to Executive Departments and Agencies on Updated Principles for Risk Analysis (Principles for Risk Analysis).[13] This memorandum was intended to reinforce the principles developed in 1995. While the focus was on actions directed at improving public health, safety, and the environment, it was noted that many of the principles were relevant to other fields, such as financial or information technology risk analyses.

The Principles for Risk Analysis reiterated the requirements for best available science as they were articulated in the Information Quality Guidelines and presented further important information regarding the use of and presentation of assumptions, judgments, and uncertainties in risk analyses. For instance, among other requirements, the Principles for Risk Analysis require that:

> Judgments used in developing a risk assessment, such as assumptions, defaults, and uncertainties, should be stated explicitly. The rationale for these judgments and their influence on the risk assessment should be articulated.[14]
>
> Results based on different effects and/or different studies should be presented to convey how the choice of effect and/or study influences the analysis. The presentation of information regarding different scientifically plausible endpoints should allow for a robust discussion of the available data, associated uncertainties, and underlying science.[15]
>
> Due to the inherent uncertainties associated with estimates of risk, presentation of a single estimate may be misleading and provide a false sense of precision. Expert panels agree that when a quantitative characterization of risk is provided, a range of plausible risk estimates should be provided.[16]

[13] See: https://georgewbush-whitehouse.archives.gov/omb/memoranda/fy2007/m07-24.pdf.
[14] Ibid, at page 8.
[15] Ibid, at page 8.
[16] Ibid, at page 6.

c. Non-Governmental Reports on Improving Science in Regulations

Improving Peer Review:
In addition to government guidance, other consensus groups have spoken to the needs for ensuring high quality science. For instance, in 2009 the Bipartisan Policy Center put out a report entitled "Improving the Use of Science in Regulatory Policy."[17] Important recommendations in this report included:

> The Administration needs to promulgate guidelines (through executive orders or other instruments) to ensure that when federal agencies are developing regulatory policies, they explicitly differentiate, to the extent possible, between questions that involve scientific judgments and questions that involve judgments about economics, ethics and other matters of policy.[18]
>
> The federal government, universities, scientific journals and scientists themselves can help improve the use of science in the regulatory process by strengthening peer review, expanding the information available about scientific studies, and setting and enforcing clear standards governing conflict of interest.[19]

In 2012, the Keystone Center released a report entitled "Improving the Use of Science in Regulatory Decision-Making."[20] This report stressed the importance of consistency and transparency in selecting peer review panels and also noted that the regulatory process is better when there is a consistent, transparent and systematic review and evaluation of the scientific literature.

The importance of a robust peer review process cannot be underestimated. Peer review is essential in the evaluation of scientific information to ensure the development of scientifically defensible assessments. It allows for the review of the underlying assumptions, methodology, criteria, and conclusions reached in the evaluation. Federal Agencies have several mechanisms available to them to conduct peer review of scientific information; however, these peer review processes and approaches are inconsistently applied, including the selection of peer review panel members and the consideration given to public and peer review comments.

For example, during some EPA peer review meetings, the peer reviewers have appeared to be overly deferential to EPA and reluctant to be seen as criticizing EPA staff. We have also seen situations where peer reviewers have suggested discounting a study solely based on the funding source, without any consideration of the quality of the study. Also, EPA staff often comment throughout peer review meetings, essentially participating as peers, while stakeholders, including industry experts, are typically excluded from the

[17] See: http://cdn.bipartisanpolicy.org/wp-content/uploads/sites/default/files/BPC%20Science%20Report%20fnl.pdf.
[18] Ibid, at page 4.
[19] Ibid, at page 45.
[20] See: https://www.keystone.org/wp-content/uploads/2015/08/091812-Research-Integrity-Roundtable-Report.pdf.

dialogue. This practice undermines the integrity of the reviewers' role as independent and external to the assessment itself.

Additionally, a critical element of peer review is the consideration of public comments. The public plays an important role in the review process by helping identify key scientific information and potential concerns with the assessment being evaluated. Unfortunately, within some Agencies, there is no robust consideration of public comments in the peer review process. For example, reviewers on the EPA Science Advisory Board (SAB) are not given clear advice regarding what it means to "consider" public comments. In fact we have seen SAB chairs ignore public input because they are not required to address it. When this has occurred, SAB staff have not clarified to the peer reviewers that they can and should respond to public input.

Improving Systematic Review:
The importance of systematic review in risk evaluation was mentioned in the 2012 Keystone Center report, and emphasized in a 2014 NAS report of its Review of EPA's Integrated Risk Information System (IRIS) Process.[21] This NAS panel noted that the use of systematic review approaches would "substantially strengthen" the IRIS process at EPA. Unfortunately, we have yet to see the IRIS program release an assessment that is consistent with these NAS recommendations.

Data Access and the Protection of Confidential Business Information:
Both the Bipartisan Policy Center report and the Keystone Center report discuss the need to protect proprietary business information. The legitimate need for protection must be balanced against public interest in the disclosure of relevant studies and data for the purposes of reproducibility.[22] The OMB Information Quality Guidelines recognize this tension and note that

> Even in a situation where the original and supporting data are protected by confidentiality concerns, or the analytic computer models or other research methods may be kept confidential to protect intellectual property, it may still be feasible to have the analytic results subject to the reproducibility standard.

When it comes to environmental, health and safety information about chemicals, the Toxic Substances Control Act (TSCA) requires that EPA have access to that information. ACC member companies' current practice is to share summary results of industry studies with EPA or to provide raw data underlying health, safety and environmental studies with EPA upon request. Thus the Agency has the information it needs to ensure the safe regulation of chemicals, and EPA can rely on this information in its regulatory decisions. While any proprietary information must be protected, there are processes that exist to make robust study summary information available to the public in a manner that is sufficient to ensure public understanding of the data and address transparency demands. When it comes to full disclosure to the public, decisions to share raw data with non-regulatory bodies are made on a case by case basis. Companies weigh factors such as the

[21] See: http://dels.nas.edu/Report/Review-Integrated-Risk/18764.
[22] See the Keystone Center report at page 20.

potential health/environmental impact of the product, the commercial value of the data, the age of the data, and other administrative, ethical, financial, legal, technical, and public health considerations.

III. Science Standards in the 2016 Lautenberg Chemical Safety Act

When the Lautenberg Chemical Safety for the 21st Century Act (LCSA)[23] was passed in 2016, it was the first time Congress directed a Federal Agency to consider not only the best available science but also the weight of the scientific evidence (WoE). These scientific standards, added to TSCA in Section 26 of the LCSA, have a prominent role in ensuring the Act achieves the fundamental objective of improving public confidence in the federal regulatory system. EPA now has a mandate to apply high quality, reliable and relevant scientific information.

To date, EPA appears to be interpreting these scientific standards as implying that "business as usual" is consistent with the standards. EPA is reluctant to explicitly incorporate the best available science and WoE standards into the framework rules that it is developing to implement the LCSA. Instead, the Agency has suggested that simple reliance on existing guidelines and current practices are sufficient to meet the standards in Section 26.[24] This is of great concern to ACC.

For example, Section 26(i) of the LCSA requires that EPA make decisions using a WoE approach. While a definition of WoE is not provided in the statute, the June 7 Congressional Record provides a definition that was entered into the record by Senator Boxer, the ranking minority member on the committee:

> Weight of the evidence means a systematic review method that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance.[25]

This definition is also consistent with the June 2015 House Report language.[26]

Importantly, the definition refers to using a systematic review approach, as has been recommended by the Keystone Center report and the NAS in 2014. It also suggests that evidence be judged on its quality.

Notably, EPA's proposed risk evaluation rule does not incorporate this definition. EPA has asked, however, for comment on this approach.

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[23] P.L. 114-182, 130 Stat. 448 (June 22, 2016).

[24] EPA's draft framework rules for prioritization and risk evaluation can be found at: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act-5.

[25] See Senate Congressional Record, June 7, 2016 at page S3518, available at: https://www.congress.gov/crec/2016/06/07/CREC-2016-06-07-pt1-PgS3511.pdf.

[26] See House Report at page 33, available at: https://www.congress.gov/114/crpt/hrpt176/CRPT-114hrpt176.pdf.

A recent example demonstrates that EPA apparently does not interpret WoE in the same way Congress did in the LCSA. In the draft risk assessment of 1-bromopropane (released prior to enactment of LCSA), EPA did not conduct a systematic review, and the draft assessment did not provide information regarding the quality of the individual studies.[27,28] Although the assessment identified some quality considerations, EPA did not provide any information regarding its own findings from its quality review of the individual studies.[29,30] Additionally, EPA did not describe how considerations were applied and what constitutes a study of "high quality" or "good quality." While EPA staff orally noted that they followed a WoE approach,[31] EPA simply chose the value that provided the lowest point of departure and thus would be most health protective.

The 1-bromopropane draft risk assessment is not consistent with the best available science or the WoE approach envisioned under the LCSA. If EPA chooses to simply follow current practices, the Agency will embark on a process that is not consistent with the new Section 26 science standards.

Section 26 requires EPA to develop, within two years of enactment, any new policies, procedures and guidance that are necessary to ensure compliance with the LCSA. In addition, within five years of enactment and then once every five years, EPA is required to review these policies, procedures and guidance. This approach will ensure that EPA is consistently relying upon scientific approaches that are consistent with the state of the science.

IV. Potential Solutions to Improving Agency Science

ACC provides the following four recommendations to improve the science supporting regulatory decision making.

a. Improve and Clarify Scientific Definitions

ACC believes that the intent of Congress in drafting the scientific standards in the LCSA is clear. It is also clear that EPA's proposed interpretation diverges from Congressional intent in important respects. Clarifying that the intent of scientific standards is to improve existing Agency practices would be useful. In addition, providing clear and specific definitions for terms like best available science and WoE would be beneficial to the consistency, reliability and credibility of EPA's regulatory decisions. These definitions should address not only what Agencies should consider when evaluating scientific information, but also what information

[27] See Comments of the American Chemistry Council on the TSCA Work Plan Chemical Draft Risk Assessment of 1-Bromopropane , Docket No. EPA-HQ-OPPT-2015-0084, May 9, 2016.
[28] See peer review report/meeting minutes available at: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2015-0805-0028, at page 41 which states: "While the Agency indicates that the literature was thoroughly reviewed for robustness, adequacy, etc., the Committee found that it is not clear what exact methodology was used to systematically rate, rank, and select studies to inform sections of the risk assessment. For example, was a quantitative ranking system developed for study quality?"
[29] Ibid.
[30] See draft available at: https://www.epa.gov/sites/production/files/2016-03/documents/1-bp_report_and_appendices_final.pdf, at Appendix M.
[31] See Chemical Safety Advisory Committee Meeting Transcript available at: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2015-0805-0027; at page 130.

Agencies should present in evaluations. Requiring the Agencies to "show their work" and present their thought process in a transparent and clear manner would be have tremendous value. For example, adopting the language from the SDWA Amendments, we suggest the following definition of best available science:

> *Best available science* means information that has been evaluated based on its strengths, limitations and relevance and that the Agency is relying on the highest quality information. In evaluating best available science, the Agency will also consider the peer review of the science, whether the study was conducted in accordance with sound and objective practices, and if the data were collected by accepted methods or best available methods. To ensure transparency regarding best available science the Agency will describe and document any assumptions and methods used, and address variability, uncertainty, the degree of independent verification and peer review.

Defining WoE clearly would also be advantageous. As noted previously, we suggest the definition articulated in the Senate debate on LCSA on June 7, 2016. When using this definition, it will also be important to clearly define the term "systematic review" as there may not be a uniform interpretation of that term among stakeholders.

A particular concern in applying the best available science and weight-of-the-evidence is the tendency of federal agencies to use default assumptions, even when data are available.

Despite more than 30 years of extensive mechanistic toxicological research by academia, research institutions and the private sector, some regulatory programs in EPA continue to rely on default approaches for hazard characterizations and risk assessments that date back to the 1970s. Even though frameworks for integrating mechanistic information and mode of action have been developed by authoritative bodies and incorporated into the EPA cancer risk guidelines,[32] at the present time, there is uneven use within EPA of such approaches in hazard characterizations and risk assessments. EPA's Office of Pesticide Programs has often determined, based on WoE evaluations that include consideration of mode of action and human relevance, that carcinogenic effects in animal studies are not relevant to humans or the carcinogenic effects are secondary to target organ toxicity, and thus no carcinogenic risks are posed to humans at doses below those which produce such toxicities. However, the IRIS program continues to rely on the 1970s default linear approach for cancer risk assessment. The IRIS program steadfast reliance on default linear approaches has significant consequences for many chemicals and can create tremendous costs to address "phantom risks" in site cleanups.[33] This outdated manner in which the EPA IRIS program deals with mode of action knowledge does not comport with use of best available science.

Therefore, in implementing the definitions of best available science and WoE for the evaluation of the potential carcinogenic effects of substances, when supported by the scientific data, EPA should present non-linear modeling approaches consistent with the available data and scientific understanding of endogenous exposures and mode of action, in lieu of, or at a minimum in addition to, a linear default. Further, such assessments should include, in addition to upper

[32] See EPA 2005 Guidelines for Carcinogen Risk Assessment
[33] See George M. Gray and Joshua T. Cohen Nature 489, 27–28, 06 September 2012.

bound calculations, the distribution of estimated hazards or risks, including central tendency values, and clear criteria for when defaults are justified, including criteria for the application of uncertainty factors.

b. Improve Oversight and Develop Quality Checklists

Considering the guidance that already exists from OMB, other consensus bodies, and within the Agencies, stronger oversight to ensure that Agencies are following existing guidance could be highly effective. This oversight could come from independent offices within Agencies, Congress, or OMB or OSTP within the Executive Office of the President. One tool that may be effective is to develop a checklist to ensure that quality standards are met in scientific evaluations that support regulations. For instance, a recent publication from former EPA scientists has suggested that to promote transparency and consistency, risk evaluations could be compared to a guide or checklist which depicts all the important elements of a high quality assessment.[34] Drs. Dellarco and Fenner-Crisp suggest that this guide "could be used by authors, sponsors, risk assessors, peer reviewers, and other interested stakeholders to determine if an assessment meets the current best scientific practices."[35]

c. Improve Peer Review Practices

As noted earlier, the importance of a robust peer review process cannot be underestimated. Ensuring that peer review panels are composed of a diverse group of experts that have the breadth and depth of experience necessary to review scientific analyses in a transparent and comprehensive manner would be beneficial. It is also important to ensure that peer reviewers are fully independent from the program office issuing the assessment and conflicts of interest are fully evaluated and disclosed. More details on improving peer review can be found in the OMB Information Quality Bulletin for Peer Review,[36] as well as in reports from other consensus bodies, as discussed in Section II.

d. Change Publication Incentives and Standards for Scientific Grants and Funding

Much has been written about the lack of reproducibility of research findings published in peer reviewed journals.[37] The trend towards "publish or perish" puts immense pressure on researchers to publish findings, and in particular to publish predominantly positive findings.[38]

Publication bias is common to published academic literature. This leads to bodies of literature in which the majority of publications support a given hypothesis. Publication bias stems from the fact there are many fewer incentives for publishing negative information or information that does

[34] See publication available at: https://ehp.niehs.nih.gov/15-10483/.
[35] Ibid
[36] See: https://www.gpo.gov/fdsys/pkg/FR-2005-01-14/pdf/05-769.pdf.
[37] See for example: http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0020124, or http://www.nature.com/news/reproducibility-1.17552.
[38] See for example: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3999612/.

not support a hypothesis. Promotions and job security in academia, as well as having grants funded by Federal Agencies, are often tied to an author's publication record.

Government Agencies can play an important role by 1) changing the incentives for grant funding such that decisions to fund research do not depend so heavily upon finding positive results and 2) putting in place standards to ensure that research studies are designed in a manner that will make them useable for regulatory decision making. Standards for funding could ensure that research studies follow best scientific practices and are designed with regulatory use in mind. For instance, for chemical risk assessment, studies should be designed to test more than three doses such that a dose-response analysis can be conducted. Unfortunately we have seen too many examples of government funded research where only one high dose is tested. While this information may have some value, it is then difficult to use these data to determine what impact the same chemical may have at more environmentally relevant lower dose ranges. If the government demanded a more robust study design when approving the research projects, the data obtained would likely be much more useful.

V. Conclusion

Ensuring that Federal decision making is firmly based on the use of high quality science is critical to helping the government meet its obligation to protect human health and the environment. This can be achieved through common sense reforms that will lead to more efficient and effective regulatory decisions. ACC looks forward to working with members of the Committee to enhance approaches to ensure that high quality science is the foundation to regulatory decision making.

Appendix 1: Examples of Scientific Concerns with Federal Science Evaluations

Below ACC provides a few specific examples where Federal Agencies have fallen short when it comes to using the best available science.

a. Case 1: OSHA Crystalline Silica PEL

Background
OSHA finalized its workplace Permissible Exposure Limit (PEL) for crystalline silica in March, 2016. The final PEL reduced the standard from 100 $\mu g/m^3$ to 50 $\mu g/m^3$.

Crystalline silica (commonly encountered as beach sand) is the second most abundant mineral in the Earth's crust. It is ubiquitous in rocks, gravel, sand and soils; plays a crucial role in construction and transportation; and is essential for many manufacturing processes and countless products. For example, it is a critical material for foundries and steel making, and is a key component of abrasives, paints, high-tech equipment, glass and ceramics.

OSHA contended that the PEL of 100 $\mu g/m^3$ was not sufficiently protective. In fact, however, the data clearly shows that the incidence and rate of silicosis mortality have declined dramatically since adoption of the 100 $\mu g/m^3$ PEL in 1971, and the remaining cases can be attributed to higher silica exposures that were prevalent decades ago (allowing for latency) and to exceedances of the 100 $\mu g/m^3$ PEL. Moreover, the best evidence indicates that for silicosis and other potential pulmonary diseases, including lung cancer, there is a concentration-based threshold for silica exposure that exceeds 100 $\mu g/m^3$.

Importance
The new PEL is not economically feasible across multiple sectors of general industry and therefore will cause significant economic disruption throughout the economy. OSHA estimated that the annualized costs for all of general industry to comply with the revised standard would be $359 million. That estimate of compliance costs is deeply flawed and vastly understates the true costs of compliance, which are likely to be more than an order of magnitude higher. It would be far more cost-efficient and effective to bring all general industry employers into compliance with the longstanding PEL of 100 $\mu g/m^3$ rather than mandating that they attempt to comply with the new PEL of 50 $\mu g/m^3$.

Scientific Concerns
Because of its long latency period, silicosis cases seen today are attributable largely to exposures that occurred decades ago – in most cases, to exposures that began before OSHA's long-standing PEL of 100 $\mu g/m^3$ was even adopted. OSHA's argument that silicosis cases are underreported does not alter the fact that silicosis cases have dropped dramatically in the previous 40+ years, as silicosis cases have been underreported relatively consistently through that same time period. There are fundamental shortcomings and limitations in OSHA's risk assessment for all of OSHA's identified endpoints of concern:

- Important statistical errors in modeling and inference, including in particular a failure to adequately control for biases, which can lead to false positive results.

- A failure to properly model exposure measurement errors, which are common in the silica worker cohort studies in particular.
- Generally, uncertainties are not well characterized in the preliminary quantitative risk assessment.
- A failure by OSHA to carry out any causal modeling or analysis that would allow it to conclude that a reduction in the PEL would actually reduce adverse health effects.

The alleged association between silica exposure *per se* and lung cancer remains controversial in the scientific community. OSHA did not properly weigh and consider the totality of the epidemiological evidence, discounting the significance of negative studies while choosing to highlight those studies that would confirm OSHA's position. Furthermore, as noted above, the best evidence points to an exposure concentration threshold for potential silica-related lung cancer that exceeds the PEL of 100 $\mu g/m^3$ that applied in general industry before the new rule was adopted in 2016.

b. Case 2: EPA IRIS Assessment of Trimethylbenzenes (TMB)

Background
On September 9, 2016, EPA issued its final report on the IRIS assessment of Trimethylbenzenes (TMBs), which addresses the potential non-cancer and cancer human health effects from long-term exposure to TMBs. Humans are not exposed to individual TMB compounds, but to complex mixtures. According to EPA, the primary uses for TMBs are as a blending agent in gasoline formulations (C9 aromatic fraction); solvents; and as a paint thinner.

In its review of TMBs, the EPA fell far short in meeting its obligations to improve its IRIS processes and assessment reports. Without explanation, EPA failed to respond to public comments on the draft TMBs assessment, even though the IRIS process for developing assessments explicitly includes a response to comments element.

Importance
As a final report, the IRIS assessment on TMBs will inform risk management decisions on TMBs by EPA's program and regional offices.

Scientific Concerns
The IRIS assessment of TMBs does not accurately represent the health effects associated with exposure to TMBs because EPA failed to utilize a consistent and transparent data evaluation procedure for evaluating and weighing the full body of evidence.

In particular, EPA failed to rely on available guideline studies on commercial complex C9 aromatic mixtures that industry conducted under EPA's TSCA program. The entire commercial C9 aromatic blend, which contains a high percentage of TMBs, has similar toxicological properties and health effects as the individual isomers of TMB. Thus, guideline studies on the commercial complex of aromatic mixtures are highly relevant to assessing the toxicology of TMBs.

EPA's Office of Pesticide Programs (OPP) has also reviewed the toxicology of TMBs and determined that the health effects of TMBs can be efficiently assessed by relying on C9 aromatic

mixture studies. OPP reached different scientific conclusions, including different quantitative health effect numbers, than that of EPA's IRIS Program. EPA, however, did not resolve these differences during the IRIS assessment of TMBs.

c. Case 3: NIOSH Cancer Policy

Background
In the NIOSH Carcinogen Policy, released in December 2016, NIOSH states that underlying this entire policy is the "recognition that there is no known safe level of exposure to a carcinogen."[39] ACC believes this statement is based on a default assumption and not clear scientific evidence, as certain carcinogens have thresholds or doses below which no adverse effects are identified.[40,41] Assuming that every chemical is toxic at high exposures and linear at low exposures does not comport with modern-day scientific knowledge of biology and there is no compelling evidence-based justification for a general low-exposure linearity. Instead, case-specific mechanistic arguments are needed.[42]

d. Case 4: EPA IRIS Assessment of Ethylene Oxide (EO)

Background
EPA posted the final IRIS Assessment of EO in December 2016. EPA, using unsupportable, conservative, risk assessment modeling, concluded that the one-in-a-million lifetime cancer risk associated with exposure to EO is far below EO background levels currently in the environment and EO levels naturally converted from ethylene in humans through breathing.

This conclusion is not plausible, and not scientifically supportable. It is based on an inadequate evaluation of a body of evidence from human studies that include historical exposure levels to

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[39] See NIOSH Carcinogen Policy available at: https://www.cdc.gov/niosh/docs/2017-100/default.html.

[40] See, for example Olden K, Vulimiri SV. 2014. Laboratory to community: chemoprevention is the answer. Cancer Prev Res (Phila). 7(7):648-52. http://cancerpreventionresearch.aacrjournals.org/content/canprevres/7/7/648.full.pdf at 650; which states: "Our understanding of toxicologic mechanisms has advanced considerably since the linear non-threshold model was adapted for cancer risk assessment. Knowledge of mechanism of action is critical for informing dose–response relationship below the experimental observable range. Johnson and colleagues (1) have used new technologies in analytical chemistry and molecular biology to characterize downstream biologic events in the exposure disease continuum. They showed that AFB1 is a classic genotoxic substance in that it binds covalently to DNA and induces mutations. In fact, DNA adduct formation exhibits a characteristic linear dose–response curve over a wide range. But, further analysis demonstrated a threshold mode of action, with respect to internal dose of active metabolite and hepatocarcinogenesis. That is, there was substantial adduct formation and DNA damage without having any affect [sic] on development of hepatocellular carcinoma."

[41] See, for example: United States Environmental Protection Agency (EPA). 2015. Chemicals evaluated for carcinogenic potential office of pesticide programs, annual cancer report. Washington, DC. http://npic.orst.edu/chemicals_evaluated.pdf. EPA has determined that a number of substances that produce cancer at high doses are not likely to be carcinogenic to humans at low doses.

[42] Rhomberg LR, Goodman JE, Haber LT, Dourson M, Andersen ME, Klaunig JE, Meek B, Price PS, McClellan RO, Cohen SM. 2011. Linear low-dose extrapolation for noncancer health effects is the exception, not the rule. Crit Rev Toxicol. 41(1):1-19. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3038594/pdf/btxc12-001.pdf and Bogen, KT. 2016. Linear-No-Threshold Default Assumptions for Noncancer and Nongenotoxic Cancer Risks: A Mathematical and Biological Critique. Risk Analysis Risk Analysis, Vol. 36, No. 3. http://onlinelibrary.wiley.com/doi/10.1111/risa.12460/pdf. .

EO that are far higher than current occupational exposure limits. Other, more accurate, data sources are available, and alternative scientific risk assessment modeling approaches could have been used, but EPA made no serious, systematic attempt to integrate all of the evidence.

Importance
A determination by EPA that EO, with a myriad of important applications including the sterilization of medical equipment for surgery, can cause cancer at less than one part-per-trillion[43] exposure will needlessly cause alarm and confusion, not only among workers, but also in the general population and in the public health and medical communities. These numbers are not reliably measurable, and are orders of magnitude below current endogenous and exogenous levels of EO.

Scientific Concerns
EPA did not adequately consider study quality into the IRIS review. Industry cohorts were not considered with the other epidemiology data sets even though this cohort was stronger than foreign cohorts used that contained occupational exposure interferences.

EPA did not fully utilize linear and non-linear modeling approaches (as allowed within the cancer assessment guidance) to estimate cancer risk from current EO exposure levels and expected DNA repair mechanisms.

EPA did not consider realistic exposure scenarios and fully delineate endogenous vs. exogenous EO and associated health impacts.

In 2007, EPA's SAB identified problems with the linear regression modeling and low dose extrapolation for determining cancer risk. The SAB concluded that substantial revisions were needed in the IRIS assessment including:

- Acquiring and using individual data for modeling rather than grouping populations for modeling that currently results in overly conservative estimated cancer risks;
- Given the distribution of and questionable association with certain cancer types, considering using both linear and non-linear approaches to estimate cancer risk;
- Providing more transparency and correcting flaws associated with inappropriately grouping lymphohematopoietic (LH) cancers and combining genders for the dose-response analysis.

In 2015, a specially selected SAB Committee reviewed a revised draft EO IRIS assessment. The committee, however, did not conduct an independent, unbiased review. Problems included:

- Inaccurate public statements by several SAB members indicating industry produced scientific studies should be disqualified due to potential industry influence, and the acceptance by SAB and IRIS staff of such a position; no evidence of biased data sponsored by industry was ever presented, and it is clear that those members advocating this position should have been disqualified due to these clear biased positions.

[43] 1 part per trillion is roughly equivalent to 1 second in 320 centuries or 1 inch in 16,000,000 miles

- Lack of understanding by SAB members of new evidence-based medicine concepts regarding mutagenicity of cancer cells and the contribution of naturally occurring EO in DNA repair mechanisms;
- Recommendation of epidemiology data sets with questionable or scientifically unsound characteristics to estimate cancer risk and rejection of alternative data sets that are as or more robust than those selected;
- EPA still did not use individual data for modeling as recommended in 2007, and did not seriously explore alternatives to the linear low dose modeling approach.

Even though the SAB made extensive recommendations in its 2015 report and public comments were submitted on the IRIS draft reviewed by the SAB, EPA still did not respond fully to all comments submitted or implement all the changes recommended by the SAB.

e. Case 5: National Ambient Air Quality Standard for Ground-Level Ozone

Background
In 2015, EPA lowered the National Ambient Air Quality Standard (NAAQS) for Ground-Level Ozone from 75 ppb to 70 ppb. Ozone, which is one of six criteria pollutants regulated under Section 109 of the Clean Air Act, is formed from a reaction between nitrogen oxide (NOx), volatile organic compounds (VOCs), and sunlight. Exposure to relatively high concentrations of ozone can cause adverse respiratory effects and interfere with plants' ability to produce and store food.

In 2008, the ozone NAAQS was set at 75 ppb. Areas were not designated as complying or failing to comply with this standard until May 2012 due to unnecessary delays following the Obama Administration's premature reconsideration of the standard in 2010. This resulted in areas across the country not being allowed sufficient time to begin implementing the 2008 standard before EPA changed the standard again, which the Agency justified as being necessary to protect public health and welfare. However, a closer look at EPA's work during this most recent review process questions the need to revise down the standard.

Scientific Concerns
EPA relied on ecological epidemiology studies, also known as time-series analyses and clinical studies, as the basis to lower the ozone NAAQS to 70 ppb in 2015. However, EPA failed to adequately characterize the uncertainties associated with adverse health effects reported in these studies. Ecological epidemiology studies are not scientifically rigorous enough and are not designed to determine if ozone was responsible for the demonstrated the health effects. Clinical studies are limited by the small sample sizes and because they do not adequately consider the normal variation in the lung function.

For example, in the 2015 standard, EPA relied on two new studies, Schelegle *et al.* (2009)[44] and Kim *et al.* (2011).[45] These studies both used a small sample which, while not unusual for a

[44] Schelegle, ES; Morales, CA; Walby, WF; Marion, S; Allen, RP. 2009. 6.6-Hour inhalation of ozone concentrations from 60 to 87 parts per billion in healthy humans. Am. J. Respir. Crit. Care Med. 180(3):265-272.
[45] Kim, CS; Alexis, NE; Rappold, AG; Kehrl, H; Hazucha, MJ; Lay, JC; Schmitt, MT; Case, M; Devlin, RB; Peden, DB; Diaz-Sanchez, D. 2011. Lung function and inflammatory responses in healthy young adults exposed to 0.06 ppm ozone for 6.6 hours. Am. J. Respir. Crit. Care Med. 183:1215-1221.

controlled human exposure study, proves difficult as a basis for drawing broader conclusions with regard to the protection of public health. EPA identified lung function decrements of only 2.8% to be adverse effects when the variation of lung function in normal subjects can vary by over 5% (Pellegrino *et al.* 2005)[46] to 17.6% (Medarov *et al.* 2008).[47] EPA must rely on biological, not just statistical, significance in identifying an adverse health and provide clear guidance on how to define adverse effects.

Ultimately, these studies did not actually support health effects below the 75 ppb standard, and EPA primarily justified the regulation impacting 300 million people on study results from just a few individuals.

[46] Pelligrino, R; Viegi, G; Brusasco, V; Crapo, RO; Burgos, F; Casaburi, R; Coates, A; van der Grinten, CPM; Gustafsson, P; Hankinson, J; Jensen, R; Johnson, DC; MacIntyre, N; McKay, R; Miller, MR; Navajas, D; Pedersen, OF; Wanger, J. 2005. Interpretive strategies for lung function tests. Eur. Respir J. 26: 948-968.
[47] Medarov BI, Pavlov VA, Rossoff L. 2008. Diurnal variations in human pulmonary function. Int J Clin Exp Med. 1(3):267-273.

Handout/L.D.May

The EPA's Science Office Removed "Science" From Its Mission Statement

BY **EMILY ATKIN**

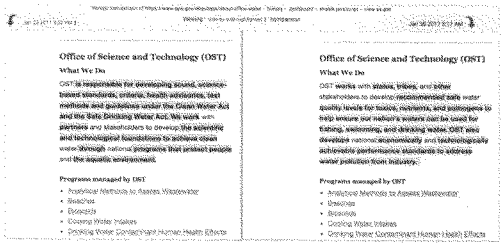
March 7, 2017

When President Donald Trump took office in late January, his administration began tweaking the language on government websites. Some of the more prominent changes occurred on Environmental Protection Agency pages—a mention of human-caused climate change was deleted, as was a description of international climate talks. The shifts were small, but meaningful; many said they signaled a new era for the EPA, one in which the agency would shy away from directly linking carbon emissions to global warming and strive to push Trump's "America First" message.

Those initial tweaks were documented by the Environmental Data and Governance Initiative, a group of scientists and academics who spend their free time tracking changes to about 25,000 federal government webpages. On Tuesday, they shared their latest finding with the *New Republic*: The EPA's Office of Science and Technology Policy no longer lists "science" in the paragraph describing what it does.

"This is probably the most important thing we've found so far," said Gretchen Gehrke, who works on EDGI's website tracking team. "The language changes here are not nuanced—they have really important regulatory implications."

The EPA's Office of Science and Technology has historically been in charge of developing clean water standards for states. Before January 30 of this year, the website said those standards were "science-based," meaning they were based on what peer-reviewed science recommended as safe levels of pollutants for drinking, swimming, or fishing. Since January 30, though, the reference to "science-based" standards has disappeared. Now, the office, instead, says it develops "economically and technologically achievable standards" to address water pollution.


Office of Science and Technology (OST)
What We Do
Programs managed by OST
Office of Science and Technology (OST)
What We Do
Programs managed by OST

Screenshot courtesy of EDGI

Gehrke said she thinks these changes speak to a long-running debate over how polluters should be regulated. Environmentalists often argue for performance-based regulations, where air and water is required to meet a certain standard of quality, no matter how companies choose to meet that standard. Gehrke says removing "science" from OST's missions and replacing it with "technologically achievable" means the EPA is moving toward more technology-based standards, where polluters just have to install certain types of technology.

Some worry these changes signal the EPA's new direction—one that prioritizes business interests over public health and science—under new Administrator Scott Pruitt, who has close ties to fossil-fuel companies. Pruitt didn't mention public health once in his first speech to agency employees, instead focusing on improving the EPA's relationship with private interests. In a tweet after his speech, Pruitt said he was

committed to working with several types of "stakeholders" on environmental stewardship. He did not mention environmentalists as one of those stakeholders.

The Union of Concerned Scientists (UCS), a science advocacy organization, shares EDGI's concerns. "The role of the EPA is to protect public health and safety," said Andrew Rosenberg, Director of UCS's Center for Science and Democracy. "So what you want a science office to do is make sure you're using the best science available, and what's safe for the public. That's a pretty critical role."

Rosenberg said it would be a "major change in direction" if the EPA stopped prioritizing the best science and focused instead on what's most "economically achievable" for businesses. "I think we have to be very mindful," he said. "It seems like this EPA and this administration broadly seem to view their job as being a support for business as opposed to safeguarding public health."

The EPA did not return our request for comment.

Emily Atkin is a staff writer at the *New Republic*. @emorwee

Post-Hearing Questions for the Record
Responses of Professor Susan Dudley,
Director, George Washington University Regulatory Studies Center

From Ranking Member Heidi Heitkamp
United States Senate, Subcommittee on Regulatory Affairs and Federal Management
Committee on Homeland Security and Governmental Affairs

"Agency Use of Science in the Rulemaking Process:
Proposals for Improving Transparency and Accountability"
March 9, 2017

1. You state in your testimony that "Congress should not delegate decisions to agencies on the pretense that science alone can make the normative determination of what policy ought to be."

   - In that vein, is codification of the EO 12866 language on "best reasonably obtainable" science a mistake? What obvious traps should Congress avoid?

I think the language in EO 12866 Section 1.b.7, which states "Each agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation," is sound guidance. It recognizes that good regulatory decisions require agencies to assess the need for and consequences of actions, and depend on different types of information – scientific as well as technical, economic, and other.

In delegating regulatory authority, legislative language should not direct agencies to base decisions on science without recognizing that other factors are also important in determining optimal solutions. (My answer to question 7 elaborates on this.)

2. The explanation in your written testimony about the two main ways science is politicized is very instructive.

   - Have there been any empirical studies about the incidence of normative versus conflated science? In your experience, is one more prevalent than the other?

I am not aware of empirical studies, and I'm not sure how one would go about measuring this phenomenon in an empirical way, but this is a very interesting question. Many criticisms of advocacy science come from industry, but one former EPA scientist, Robert Lackey, now professor emeritus at Oregon State University has spoken compellingly on what he calls "normative science." Here are 2 short pieces: http://fw.oregonstate.edu/system/files/u2937/2004c%20-%20Normative%20Science%20-%20Reprint%20-%20Lackey.pdf, http://fw.oregonstate.edu/system/files/u2937/2013a%20-%20Normative%20Science%20-%20OSU%20Terra%20Magazine%20-%20Reprint%20-%20Lackey.pdf.

My working paper provides quotations from former EPA Clean Air Scientific Advisory Committee members who raise similar concerns. https://regulatorystudies.columbian.gwu.edu/regulatory-science-and-policy-case-study-national-ambient-air-quality-standards

3. Your testimony explains how policymakers and the public may be unaware how deliberations beget false or misleading statements of certainty. Experience suggests that these discussions are then subsequently further simplified by news media and interest groups.

    - Do you have any ideas for increasing scientific and policy-making literacy among a diverse electorate and population?

Greater transparency in the models, assumptions, and risk assessment policy choices could inform the public and policy makers and encourage more open, constructive debate on those choices. One way to make risk assessment policy choices more transparent to the public as well as decision makers would be for agency scientists to calculate and present multiple risk estimates based on a variety of scientifically plausible data sets, endpoints, models, etc. (This is something GW Public Health professor George Gray & I suggested in a chapter of a 2012 book, *Institutions and Incentives in Regulatory Science*, Lexington Books, edited by Jason Johnston. I am trying to get the Subcommittee a copy of that volume, which has other articles you may find relevant.) Once a range of plausible risk outcomes is identified based on different scientifically plausible inputs, agencies could transparently identify which set of inputs, models, and outcomes comported with their preferred risk assessment policy choice. Policy officials would choose specific numerical values from a range of scientifically plausible risk estimates and publicly defend the policy choices that support that choice. This would not only provide the public information on the range of risks that scientifically defensible inputs predict, but it would provide policy officials a serious incentive to look into estimates of risk, consult with a broad variety of experts to understand the range of scientific views, and explicitly articulate the policy preferences informing their decisions.

Legislation you have introduced that requires advanced notices of proposed rulemaking could encourage 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. Your bill requiring "prospective-retrospective" analysis could also provide the public valuable information on which key assumptions will benefit from follow up analysis and feedback.

4. If one accepts the premise that key stakeholders too often dominate public comment periods and highly complex scientific deliberations in rulemaking, this begs the question about outcomes.

    - Is there academic literature exploring whether this dynamic brings about balanced and fairly compromised outcomes?

I've spoken with colleagues who know this literature better than I. They say there is mixed evidence regarding whether comments matter (some studies find they matter, others less so). There is some evidence that business/industry comments matter more than others (e.g., when

industry is in agreement, industry comments matter), though that may reflect the level of detail and analysis provided by industry compared to other commenters.

A 2012 Keystone Center report offers a series of recommendations on "the composition of committees that are empaneled to review the science behind a regulatory decision" that may be relevant to this question. (https://www.keystone.org/images/keystone-center/spp documents/Health/Research%20Integrity%20Rountable%20Report.pdf) Acknowledging the importance of choosing panelists that "have the knowledge, training, and experience needed," it admonished agencies "to recognize that all potential panelists will have conscious and unconscious biases," and said that "the panel selection process requires review of the disclosed information and a judgment as to the ability of each prospective panelist to participate in open discussion and to consider other perspectives." It encourages a range of perspectives, background, and opinion.

- Alternatively, are you aware of any empirical evidence that greater involvement by average Americans will result in different outcomes?

According to my colleagues, when average Americans get involved, they tend to do so via mass comment campaigns that are started by interest groups. Such comments don't add much, if any, legal/technical value, but can signal political problems (i.e., there is a big constituency out there that cares in a particular way, an awareness that could affect an agency that is worried about congressional oversight). There are case studies of specific rulemakings where mass comment campaigns apparently affected the content of the rule. (They mentioned USDA's organic rulemaking from years ago).

Cornell's Regulation Room is an interesting effort to engage average Americans in rulemaking. http://regulationroom.org/

5. There is a continuing increase in the number of claims deeming data and science provided by industry and used by agencies in rulemaking, to be Confidential Business Information (CBI) or proprietary. This of course prevents agencies from publicly disclosing such information in conflict with everyone's stated desire for greater transparency.

    - Should we require that each new and existing CBI claim be fully justified by its owner—that is make them explain how and why disclosure would do irreparable harm?
    - How do we get around the need for agencies to access information and science from industry that businesses legitimately don't want to provide to competitors?

I don't have enough expertise in CBI to be very helpful here. One concern may relate to the purpose of the requests, as agencies sometimes seek detailed operating information in order to write more prescriptive regulations, rather than to set performance-based standards (as encouraged by EOs 12866 and 13563).

6. The issue of regulatory resources is very important to me. Imposing new administrative rulemaking procedures often triggers demands for additional agency or OIRA resources. Where science is concerned, it becomes even more complex. For example, some agencies neither sponsor or directly conduct scientific investigation but rather outsource research by

necessity and depend heavily upon external entities to provide information needed to inform rulemaking.

- In your view, what resources are most important (i.e. funding, personnel, other)?

Parkinson's Law – that work expands to fill the time available for its completion – may be insightful here. Perhaps setting better priorities could help agencies focus existing resources in areas where 1) public problems demand a government solution because they cannot be addressed through private action, and 2) additional scientific research could reduce key uncertainties and improve regulatory decisions (the value of information or VOI concept http://lesswrong.com/lw/85x/value_of_information_four_examples/). Also, soliciting input earlier in the regulatory process (e.g., through advanced notices of proposed rulemaking) could leverage expertise from a variety of sources.

7. Your testimony includes an explanation that "The Clean Air Act directs EPA to set National Ambient Air Quality Standards (NAAQS) to "protect public health" with an "adequate margin of safety," but the agency falls prey to the science charade.

   - Is the problem here in part one of Congressional excess in statutory drafting? Would anything be different if Congress mandated that EPA merely "promote" instead of protecting public health?

I think the problem is that the language, as interpreted by EPA and the Supreme Court, does not recognize that considerations other than the health effects of exposure are relevant to the decision. If the legislative standard were conceptually to separate risk assessment from risk management, discussions over the proper standard would be more transparent. To do that, the legislation would direct agencies first to assess risks under different scenarios and then to choose a level appropriate to protect public health, taking into account a) the risk reduction achievable from reductions (from the risk assessment step), but also b) the associated benefits, c) the feasibility of controls, and d) the costs of achieving the standard.

Some statutes directed at health, safety and environmental risks have facilitated more rational regulatory policy than others by recognizing that risk management requires normative judgments that consider tradeoffs. For example, the Safe Drinking Water Act requires EPA to consider the costs as well as the benefits of requiring local water authorities to install controls for specific substances. Perhaps that is one reason why the debates over drinking water standards are generally less acrimonious than debates over ambient air quality standards. Since the statute allows explicit consideration of tradeoffs when setting standards, the full burden of decision-making is not vested in the risk assessment. As a result, policy makers and interested parties may have less incentive to embed policy preferences in the risk assessment portion of the analysis, because they can debate them openly and transparently in the risk management discussion.

Codifying current executive requirements for performing regulatory impact analyses, including benefit-cost analyses, could provide a "supermandate" that would require agencies to explicitly present uncertainties and tradeoffs and to justify decisions in a transparent manner.

Post-Hearing Questions for the Record
Submitted to Andrew Rosenberg, Ph.D., Director, Center for Science and Democracy, Union of Concerned Scientists

From Ranking Member Heidi Heitkamp
United States Senate, Subcommittee on Regulatory Affairs and Federal Management
Committee on Homeland Security and Governmental Affairs

"Agency Use of Science in the Rulemaking Process: Proposals for Improving Transparency and Accountability"
March 9, 2017

1. Your organization has methodically identified numerous instances in which good science was undermined or thwarted by politics from within government, or by powerful stakeholders who exert undue influence over scientific research and advisory bodies.

   - How do we prevent such lapses keeping in mind the interplay of influence among agencies and regulated entities?

Preventing such lapses requires a stronger commitment to scientific integrity throughout the regulatory process by which policy grounded in science is advanced. Whether the attempts to undermine good science come from within or outside of government, a more robust commitment to scientific integrity within regulated agencies would make it more difficult to undermine the science. Broadly, there are four main elements to improving commitment to scientific integrity within agencies: creating a stronger culture of scientific integrity, promoting independent science, increasing transparency, and enhancing public participation in the rulemaking process. All agencies should have a strong scientific integrity policy, ensure that all employees are made aware of the protections within the policy, fully implement and uphold the policy's core principles, and regularly evaluate and update the policy. Additionally, agencies may strengthen their commitment to scientific integrity by improving disclosures of conflicts of interest in the peer review process and on federal advisory committees. For peer reviews, it would be beneficial if it were required that all persons in peer review disclose financial ties to interests potentially affected by the review. Agencies should consider these disclosures and avoid conflicts to the greatest extent possible. Minimization and better disclosure of conflicts of interest for federal advisory committees would also be beneficial—one mechanism for increased transparency would be to make any conflict of interest waivers granted for committee members easily accessible on a public online portal.

Right now, Congress has a great opportunity to ensure that scientific integrity in research and policymaking is protected. Introduced earlier this year, S. 338 would help ensure agencies have appropriate scientific integrity policies in place so that federal scientists and policymakers could help prevent political interference in the policymaking process. The Senate can also help strengthen transparency measures at federal advisory committees by passing H.R. 70, the Federal Advisory Committee Act Amendments of 2017, which passed the House earlier this year by voice vote.

2. One of the things that all of you raised in testimony is the need to strengthen government-wide and agency scientific integrity and conflict of interest policies.

   - Should this be the responsibility of the White House and OMB, or is there a role for Congress to play?

The role of strengthening scientific integrity and protecting policymaking from political interference need not be limited to one branch of government. Both the White House and Congress can use their respective authorities to help advance scientific integrity in government policymaking.

Currently, there are bills in both the House and Senate that would codify the institution of federal agency scientific integrity policies, thus protecting this requirement in perpetuity. These bills are a positive step forward and contain several important elements. For example, one provision of both bills requires that agencies develop procedures to "identify, evaluate the merits of, and address instances in which the scientific process or the integrity of scientific and technological information may be compromised." Not all agency scientific integrity policies have created strong procedures for investigating and addressing allegation of abuses of scientific integrity, and passing a law that requires agencies to create these procedures would help to eliminate problems that have arisen within certain agencies because of lack of clarity on the topic.

There is also space for the White House to take further action on scientific integrity. The president should appoint an assistant director within the White House Office of Science and Technology Policy to coordinate and oversee policies and procedures for ensuring that federal actions are informed by the best available science without undue political influence. The White House and Congress could also forge a partnership to strengthen scientific integrity, by maintaining a commitment to whistleblower protection and preventing retaliation for making allegations related to scientific integrity policies, for example.

3. The Union of Concerned Scientists has raised transparency concerns related to media access to government scientists and how changes in journalism create barriers.

   - Keeping in mind what we've heard about the roles of scientists and policy makers, do you have any ideas on how agencies can be more responsive to journalists seeking agency comment or reaction during reporting?

There are several ways in which agencies can be more responsive to journalists seeking agency comment or reaction during reporting. One place for improvement would be for agencies to amend their media policies to remove preapproval as a required condition for interviews. Not all agencies have this requirement, but forcing journalists and their scientific sources within agencies to navigate through public information officers can— sometimes intentionally, sometimes unintentionally—hamper reporting on agency science. If agency public information officials *do* deny interviews, they should inform the journalist of the reason for their decision.

Additionally, agencies should allow journalists to interview the relevant experts, rather than respond to the journalist with talking points or directing the journalist to other employees. It would also be helpful for agencies to define "reporter" broadly enough to include freelance journalists and new media, since they are sometimes denied the access offered to traditional media outlets. There was also a case recently where the FDA used a close-hold embargo; this practice is problematic and agencies should refrain from using it.

4. Much of the discussion about scientific integrity and transparency focuses on the natural and physical sciences

   - In general, do you believe the social sciences, computer science, various engineering fields and other disciplines are equally rigorous in applying scientific principles?

In general, the same rigorous scientific principles apply across all sciences, whether the distinction is made between "hard" and "soft" sciences or between the physical sciences and other sciences. The rigor involved in the scientific process does not change because the subject being studied is different. However, it is not feasible for Congress to legislate one-size-fits all scientific standards.

   - How do we craft standards of conduct and performance that take into account any differences?

The same standards of conduct and performance should be followed by all scientific disciplines. As I outlined in my testimony, a rigorous and credible scientific process relies on the design of the study, analytical methods, methods of inference, and the provenance of the work with regard to potential conflicts of interest, peer reviews conducted and a comparison of the established literature on the subject. The scientific rigor is not determined by the field of study, but rather the way in which the scientific process is employed. These standards are well-adhered to by scientists in the community, but I believe it is difficult, if not impossible, for Congress to legislate some type of "gold standard." There needs to be a certain amount of deference given to the scientific community in crafting and implementing standards of scientific integrity.

5. There is a continuing increase in the number of claims deeming data and science provided by industry and used by agencies in rulemaking, to be Confidential Business Information (CBI) or proprietary. This of course prevents agencies from publicly disclosing such information in conflict with everyone's stated desire for greater transparency.

   - Should we require that each new and existing CBI claim be fully justified by its owner—that is make them explain how and why disclosure would do irreparable harm?

Yes.

   - How do we get around the need for agencies to access information and science from industry, information and science that businesses legitimately don't want to provide to competitors?

- How do we get around the need for agencies to access information and science from industry, information and science that businesses legitimately don't want to provide to competitors?

Agencies already can protect legitimate confidential business information and should be given deference to set up procedures that make the most sense for the businesses that they work with and/or regulate. There is nothing wrong with businesses wanting to protect confidential business information and proprietary information (this goes for scientists as well). But it is important that we do not allow businesses to overuse CBI and proprietary claims to avoid disclosing critical information that would help agencies finalize science-based policies.

6. At the hearing, one witness said that since most Personally Identifiable Information (PII), Confidential Business Information (CBI) or proprietary data used in scientific research for rulemakings, is electronically formatted, it can be easily redacted to permit public access.

    - Do you agree with this assertion?

No.

Post-Hearing Questions for the Record
Submitted to Dr. Nancy Beck, Senior Director, Regulatory Science Policy, American Chemistry Council

From Ranking Member Heidi Heitkamp
United States Senate, Subcommittee on Regulatory Affairs and Federal Management
Committee on Homeland Security and Governmental Affairs

"Agency Use of Science in the Rulemaking Process: Proposals for Improving Transparency and Accountability"
March 9, 2017

1. One of the issues discussed at the hearing is codifying language currently contained in Executive Order 12866 concerning the "best reasonably obtainable" science.

   - Do you believe this is necessary and desirable? If so, do you see any potential pitfalls if Congress takes this step?

Response: Yes. It would be very helpful to codify the agencies' commitment to rely on the "best reasonably obtainable science". What constitutes the "best reasonably obtainable science" in any particular area/matter will be relative as different fields have different standards of excellence. In addition, science is always changing. However, this should not prevent agencies from committing to rely upon the highest quality evidence. Within any given discipline, one can always establish clear criteria by which to judge the quality of scientific information, based on current standards (e.g., results of peer review, clarity of assumptions, and discussion of uncertainties). Using clear criteria, one can objectively and transparently evaluate evidence and subsequently ensure reliance on the best evidence. Codifying best available science will establish a mandate that the agencies use clear criteria to evaluate and choose the highest quality and most relevant information.

With an approach like this, the criteria will be stated and the evaluation results will be clear and documented. Experts will be able to look back over time and see what the criteria were at a certain point and then update evaluations, and perhaps change decisions, as scientific standards evolve. Relying on what is known to be the "best reasonably obtainable science" seems like a common sense approach to ensuring that the science to support rulemakings is strong. I see no pitfalls in codifying this language.

Finally, please note that in responding to this question I am interpreting "best reasonably obtainable science" and "best available science" as being essentially equivalent. While Executive Order 12866 (1993) uses the term "best reasonably obtainable scientific, technical, economic, and other information," the OMB Information Quality Guidelines (2002), consistent with the Safe Drinking Water Act Amendments (1996), uses the term "best available science." "Best available science" is also used in Executive Order 13563 (2011). The Lautenberg Chemical Safety Act (LCSA) (2016) also uses the term "best available science". For consistency, ACC recommends use of the term "best available science."

2. Your written testimony notes that stakeholders and indeed consumers may lose confidence in government if regulatory decision making is not based upon the best available and highest quality science. My question is twofold.

    - First, is an agency or the regulated community ideally best able to determine what constitutes the best or highest quality? Second, what more can agencies do to make sure they are explaining the science they are relying upon in clear terms understandable to the general public?

Response: Innovation and scientific advancement often takes place in the private sector – and it would be a mistake for an agency to ignore the private sector's input in determining what is the best available science. Similarly, industry can benefit greatly by coordinating and collaborating with Agencies. Thus agencies should work with the public, including the regulated community, when making determinations about what constitutes best or highest quality science. If the agency is considering criteria to evaluate evidence, the public should have an opportunity to comment on and provide input to inform these criteria.

There is much more the agencies can do to make sure that the science they are relying upon is understandable to the public. First and foremost is improving the clarity and transparency about scientific decision making. This includes providing clear descriptions of why certain scientific information was preferred over other information. It is for this reason that ACC recommends providing a definition for best available science in the regulatory text of the EPA framework rules that will implement the LCSA.

3. I agree with your assertion that "improving Federal Agency science should not be as challenging as it has been. Significant governmental and non-governmental guidance already exists," but is not always followed.

    - To what extent if any is this problem attributable to inadequate Congressional oversight of agencies or resource constraints?

Response: While I don't think the problem is due solely to inadequate oversight, greater congressional and public oversight would increase the pressure for agencies to be accountable when it comes to following governmental and non-governmental guidance. Resource constraints are likely not a concern here; however, perhaps with more resources, agencies could have stronger internal oversight mechanisms to ensure that their practices and approaches are consistent with best practices.

4. As you know, this Subcommittee looks at regulatory policy across the entire government. So while I agree with the need for better risk analysis and peer review, the fact is not every regulator has, or needs a Scientific Advisory Board, Panel or Commission.

- How do we improve the overall rigor of regulatory analyses without making every agency jump through hoops simply to issue a subject matter rule based upon widely accepted technical and scientific consensus?
- Do you have any concerns that imposing a stringent uniform statutory standard of scientific practice and investigation on all agencies invite frivolous debate about matters of science long since settled or yet to be thoroughly investigated?

Response: Many rules rely on risk evaluations or other influential scientific assessments. Using transparent and open public comment and peer review processes can provide confidence that the scientific underpinnings are robust, without the need for extensive requirements that could hamper appropriate regulatory action.

A uniform standard that lays out the criteria that are used to evaluate "best available science" or high quality information should not invite frivolous debate, unless of course a scientific matter was settled based on information that was not the highest quality at the time. For instance, to say that "best available science" was used means that the information was evaluated based on its strengths and limitations and relevance. Ensuring that the agency relied on the highest quality information should not be seen as too stringent—it should be seen as ensuring that the best information was used. The agencies should be able to describe the practices and criteria they will use to evaluate scientific evidence (e.g., was it peer reviewed, did it discuss uncertainties) and this transparency should help to focus the dialog on discussions about the scientific evidence.

5. There is a continuing increase in the number of claims deeming data and science provided by industry and used by agencies in rulemaking, to be Confidential Business Information (CBI) or proprietary. This of course prevents agencies from publicly disclosing such information in conflict with everyone's stated desire for greater transparency.

   - Should we require that each new and existing CBI claim be fully justified by its owner—that is make them explain how and why disclosure would do irreparable harm?
   - How do we get around the need for agencies to access information and science from industry that businesses legitimately don't want to provide to competitors?

Response: Agencies do have criteria by which they evaluate CBI claims. For example, EPA's criteria under the Toxic Substances Control Act (TSCA) is set forth at 40 C.F.R. 2.208. That criteria does not include "irreparable harm," but rather requires a company claiming CBI to demonstrate (among several other criteria) that disclosure of the information is "likely to cause substantial harm to the company's competitive position or the information is voluntarily submitted and its disclosure would be likely to impair the Government's ability to obtain necessary information in the future."

Many companies conduct research that may not be in the public domain. Companies may seek to voluntarily submit that scientific research and results to agencies for their consideration, and most, if not all, agencies want to have access to those scientific results. That research has

potentially significant economic value to the company that has a proprietary interest in it. Company's competitors should not have free access to that research without first providing the data owner with data compensation. Agencies can and should be willing to either redact the relevant commercially sensitive material from the research before making it public or make public a robust study summary that recaps the research and its findings. In these circumstances, if an interested person wanted to personally review the proprietary material first-hand to verify the public characterizations of the research, agencies' should require those interested persons to sign a confidentiality agreement that included a requirement that the interested person not use the information for any other (competitive intelligence) purpose, subject to financial penalties.

The recent amendments to the Toxic Substances Control Act require submitters to substantiate CBI claims upfront – and notably requires EPA to review all claims to protect confidential chemical identity from disclosure, and a representative subset of all other claims.
It is possible for the agencies to access information that businesses legitimately do not want to provide to competitors. This is the current practice and ACC trusts that the agencies have the capability to handle this information, and rely upon it as needed, while still protecting CBI.

6. Here in the regulatory space, the issue of agency resources is always present.

   - What resources are needed to ensure that agencies which rely upon science have access to the best reasonably obtainable research data and tools?
   - What additional resources does OIRA need to assess the veracity of agency decision-making based in part or whole on scientific evidence?

Response: Existing resources should be sufficient to ensure agencies rely upon high quality science and have access to research data and tools. Agencies currently search for and access a large amount of scientific information. Ensuring this information is the highest quality or "best available" simply comes down to how the agencies choose what information they rely upon and how the agencies justify their choices. Improving the transparency of the process to make those decisions will also be required.

Policy analysts, economists, statisticians, and scientists at OIRA currently strive to assess the veracity of scientific evidence relied upon in regulations. With more resources, particularly more FTE's, OIRA would likely be able to provide a more in-depth and thorough review of the underlying scientific analyses.

7. Much of the discussion about scientific integrity and transparency focuses on the natural and physical sciences

   - In general, do you believe the social sciences, computer science, various engineering fields and technical disciplines are equally rigorous in applying scientific principles? If not, how do we craft one size fits all standards of conduct and performance that take into account any differences?

Response: Social sciences, computer sciences, and other engineering and technical fields should be rigorous when applying scientific principles, especially when this information will support regulatory decision making. A definition for high quality or best available science, such as the one provided in response to question 4, can easily be adapted and applied to many different technical fields. A standard that requires Agencies to rely on the highest quality evidence, and to transparently justify their choices of scientific evidence, within a particular field, should not be overly burdensome. Once there is a standard of conduct making reliance on high quality information mandatory, technical experts within agencies can then define the criteria that will be used to define what high quality evidence should look like. All the criteria need not be part of the broad standard of conduct and performance.