

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.

¹ Holt, R. Testimony Before the Committee on Science, Space and Technology. February 7.

² Heath, D. Contesting the Science of Smoking. 2016. *The Atlantic*, May 4. Online at www.theatlantic.com/politics/archive/2016/05/low-tar-cigarettes/481116/, accessed March 1, 2017.

³ U.S. Surgeon General. 2014. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General, 2014. Online at www.surgeongeneral.gov/library/reports/50-years-of-progress/, accessed March 1, 2017; Institute of Medicine. 2001. Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction. National Academy Press: Washington, D.C.; U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute. 2001. Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine. Smoking and Tobacco Control Monograph No. 13. Bethesda, MD, November; Thun, M.J., C.A. Day-Lally, E.E. Calle, W.D. Flanders, and C.W. Heath, Jr. 1995. Excess mortality among cigarette smokers: changes in a 20-year interval. *American Journal of Public Health*, 85(9):1223-1230, September.

⁴ Dockery, D.W., C.A. Pope, X. Xu, J.D. Spengler, J.H. Ware, M.E. Fay, B.G. Ferris, Jr., and F.E. Speizer. 1993. An Association between Air Pollution and Mortality in Six U.S. Cities. *New England Journal of Medicine*, 329: 1753-1759. doi: 10.1056/NEJM199312093292401.

⁵ U.S. Environmental Protection Agency, Office of Air and Radiation. 2011. The Benefits and Costs of the Clean Air Act from 1990 to 2020, Revision A. Online at www.epa.gov/sites/production/files/2015-07/documents/fullreport_rev_a.pdf, accessed March 1, 2017.

⁶ Rowland, C. 2013. House GOP demands Harvard Study data. *Boston Globe*, September 7.

⁷ Goldman, G.T., E. Berman, M. Halpern, C. Johnson, Y. Kothari, G. Reed, and A.A. Rosenberg. 2017. Ensuring scientific integrity in the age of Trump. *Science*, 355(6326): 696-698, February 17.

⁸ Goldman, G., G. Reed, M. Halpern, C. Johnson, E. Berman, Y. Kothari, and A. Rosenberg. 2017. *Preserving scientific integrity in federal policymaking: lessons from the past two administrations and what's at stake under the Trump Administration*. Cambridge, MA: Union of Concerned Scientists. Online at www.ucsusa.org/sites/default/files/attach/2017/01/preserving-scientific-integrity-in-federal-policymaking-ucs-2017.pdf, accessed March 1, 2017.

⁹ Grifo, F., T. Donaghy, P. Baur, M. Halpern, K. Kaufman, M. McCarthy and C. Wexler. 2008. *Federal science and the public good: Securing the integrity of science in policy making*. Cambridge, MA: Union of Concerned Scientists. Online at www.ucsusa.org/sites/default/files/legacy/assets/documents/scientific_integrity/Federal-Science-and-the-Public-Good-12-08-Update.pdf, accessed March 1, 2017.