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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
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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. 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”
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).


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

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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 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

¹² Lackey 2013.
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....”

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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.” 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” 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, 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.

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16 Also called the “naturalistic fallacy,” the “positive-normative fallacy,” Hume’s Law and Hume’s Guillotine.
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, 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.” 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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“This transparency would both help force values debates into the open and could limit spurious claims about, and attacks on, science.”

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.

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. As reports from both the BPC and the Keystone Center emphasized, the questions posed to such panels “should

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22 Bipartisan Policy Center, 2009:5.
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/$File/sabso-casac_memo_and_comments.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/Vanessa%20Memo_03-16-06/$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,
assumptions, etc. long before any policy decisions are framed, and “positions” established.\textsuperscript{31} Advanced notices of proposed rulemaking could be used effectively to gather such input.\textsuperscript{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.”\textsuperscript{33} Acknowledging the importance of choosing panelists that “have the knowledge, training, and experience needed to address the charge to the panel,”\textsuperscript{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.”\textsuperscript{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.\textsuperscript{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,
relying on differences in treatments (such as differences in attainment status with NAAQS) can inform risk assessments going forward.\textsuperscript{37}

\textbf{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.\textsuperscript{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.\textsuperscript{39} These disclosure policies appear to improve the reproducibility of the results of published papers.\textsuperscript{40}

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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.”\textsuperscript{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.

\textsuperscript{39} Dudley et al, 2017, Tip 6.