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Hearing on

Fostering Quality Science at EPA: Perspectives on Common Sense Reforms

Before

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Committee on Science, Space, and Technology
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Statement of Susan E. Dudley

Chairman Harris, Ranking Member Miller, and Members of the Subcommittee, thank you for inviting me to testify today on "Fostering Quality Science at EPA: Perspectives on Common Sense Reforms." I am Director of the George Washington University Regulatory Studies Center and Research Professor in the Trachtenberg School of Public Policy and Public Administration.*

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

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

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

> Political decision-makers should never dictate what scientific studies should conclude, and they should base policy on a thorough review of all relevant research and the provisions of the relevant statutes. But some disputes over the "politicization" of science actually arise over

* 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.

> differences about policy choices that science can inform, but not determine. (BPC 2009, 4)

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

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

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

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

While some judgment is necessary to translate scientific evidence into risk assessment, current risk assessment policies lead to distortions in risk estimates and false precision in the presentation of scientific information. This threatens the scientific credibility of the process, hiding rather than making transparent the

uncertainty in assessments of risk, putting key policy choices in the hands of staff, and allowing policy makers to avoid making hard decisions.

When questions involving policy judgment and values are falsely characterized as scientific, a small number of people have an effective monopoly on the information that is used and how it is characterized, leading to decisions that are not as accountable or as transparent as they should be. "When regulators purport to rely on science as the sole basis for their policy choices, the real reasons justifying their choices remain hidden from public view." (Coglianese 2009) This is exacerbated by the adversarial nature of rulemaking, and group dynamics that discourage differences of opinion and lead to poor decisions that mask uncertainty and give short shrift to important factors and perspectives.

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

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

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

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

A. politicians attempting to control science ("politicization of science"), or
B. scientists attempting to control policy ("scientification of policy.")

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

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

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

Altering these incentives is challenging, and I appreciate this Subcommittee's interest in this subject. In a chapter of a forthcoming book,[†] my coauthor Professor George Gray and I offer modest suggestions aimed at increasing transparency in regulatory science, strengthening the checks and balances provided by different participants in the rulemaking process, and engaging a broad range of expertise and perspectives to

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

counter the problems insular decision-making brings. Those suggestions are the basis for a few recommendations to the Subcommittee.

1. **Recognize that "science" is a positive discipline that can inform, but not decide, appropriate policy. Avoid the temptation to delegate decisions to agencies on the pretense that "science" alone can make the normative determination of what policy should be.**

The BPC observed:

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

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

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

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

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

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

The BPC recommended:

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

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

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

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

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

Successful reforms might involve pre-rulemaking disclosure of risk assessment information, to engage broad public comment on the proper choice of studies, models,

assumptions, etc. long before any policy decisions are framed, and "positions" established.

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

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