WRITTEN TESTIMONY OF

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FOSTERING QUALITY SCIENCE AT EPA: PERSPECTIVES ON COMMON SENSE REFORM

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Testimony of Gary E. Marchant, J.D., M.P.P., Ph.D

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

The Critical Role of Science at EPA

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

increasing demand for, and the supply of, scientific inputs into environmental regulatory decision-making will surely continue and even accelerate for the foreseeable future.

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

The Institutional Context of Science

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

[1] Cary Coglianese and Gary E. Marchant, *Shifting Sands: The Limits of Science in Setting Risk Standards*, 152 PENN. L. REV. 1255-1360 (2004).
[2] Wendy E. Wagner, The Science Charade in Toxic Risk Regulation, 95 COLUMBIA LAW REVIEW 1613-1723 (1995).
[3] Robert M. Sussman, *Science and EPA Decision-making*, 12 JOURNAL OF LAW AND POLICY 573-587 (2004).

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

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

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

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

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

interests, and openly acknowledging uncertainties and limitations of the data and resulting findings.

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

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

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

accordingly recommended that "regulatory agencies take steps to establish and maintain a clear conceptual distinction between assessment of risks and consideration of risk management alternatives" (p.3).

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

Successful Examples of Separating Science from Policy

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

The Health Effects Institute (HEI) is a nonprofit corporation created in 1980 to provide independent research on air pollution issues that is co-funded by EPA and the automobile industry. The objective of the HEI was to provide "high-quality, impartial, and relevant science on the health effects of air pollution."[7] Although HEI was initially a purely research organization, it subsequently assumed a secondary function of providing neutral scientific

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

assessments of controversial issues. The HEI's commitment to providing a neutral, objective scientific assessment of controversial air pollution issues, implemented through both its organizational structure and procedures, has made it a highly-regarded and credible "honest broker" on air pollution science.[8]

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

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

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

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[8] Terry J. Keating, *Lessons from the Recent History of the Health Effects Institute*, 26 SCI TECH. HUM. VALUES 409-430 (2001).
[9] EUROPEAN FOOD SAFETY AUTHORITY, ABOUT EFSA, http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_AboutEfsa.htm .
[10] *Id.*
[11] *See, e.g.*, Ragnar E. Lofstedt, *A European Perspective on the NRC "Red Book," Risk Assessment in the Federal Government: Managing the Process*, 9 HUM. & ECOLOGICAL RISK ASSESSMENT 1327, 1332 (2003).

objectivity, as seen by the commitment in its Mission Statement "to the core standards of scientific excellence, openness, transparency, independence and responsiveness."[12]

A Proposed Institute for Scientific Assessments

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

The ISA would be an independent, stand-alone scientific assessment body that can provide highly valuable and credible scientific input into the regulatory process. It would be structurally and procedurally designed to limit its activities to scientific matters and to resist any temptation to stray into policy advocacy. The ISA would be staffed and managed by full-time federal employee scientists hired using an independent process based on scientific merit, and overseen by an external advisory board that would include prominent national scientific experts, such as the leaders of the National Academy of Sciences (NAS) and the American Association for the Advancement of Science (AAAS).

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

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[12] EUROPEON FOOD SAFETY ADMINISTRATION, MANAGEMENT PLAN OF THE EUROPEAN FOOD SAFETY AUTHORITY FOR 2008 7 (2007), *available at* http://www.efsa.europa.eu/cs/BlobServer/DocumentSet/mb_managementplan2008-adopted,3.pdf?ssbinary=true.

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

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

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

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

I also acknowledge in my new chapter that the "creation of an ISA would no doubt raise a number of administrative and procedural issues. For example, what if a regulatory agency wanted to depart from the scientific findings of the ISA? What opportunity would there be for

public comment and perhaps even judicial review of ISA assessments? Could a party challenging in court an agency regulation that relied on an ISA assessment raise claims against the ISA assessment on the merits? These and other issues would require careful consideration." However, there are models and approaches to address these implementation issues, and the potential benefits for improving the credibility of EPA's science may justify this type of institutional change.

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