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Before

U.S. House of Representatives
The Committee on Science and Technology
Subcommittee on Investigations and Oversight

April 30, 2009

On

The Role of Science in Regulatory Reform

Mr. Chairman, Ranking Member Broun, and Members of the Subcommittee, I am pleased to appear before you today to discuss the role of science in setting regulatory standards. In my testimony, I will seek to offer some conceptual clarity about the contribution of science to the making of regulatory policy, explaining what science can and cannot be expected to accomplish in regulatory decision making.

Good regulation aims to – and does – solve problems.[1] Making sound decisions about regulation therefore calls for an understanding of the problem a regulator seeks to solve. What is the scope and severity of the problem? Is the problem growing worse? What are the causes of the problem? These kinds of questions call for accurate and

[1] John Braithwaite, Cary Coglianese, and David Levi-Faur, "Can Regulation and Governance Make a Difference?," *Regulation & Governance* 1: 1, 4 (2007).

relevant information about the current state of the world as well as evidence confirming theories about cause-effect relationships.

In addition to understanding the problem, regulatory decision making calls for a consideration of solutions.[2] What are the possible ways the problem might be solved (or at least the situation improved)? Against which criteria ought alternative solutions be judged (including the option of doing nothing)? How does each alternative fare when assessed against the chosen criteria? On the basis of answers to these kinds of questions, the regulator can make an informed decision about what ought to be done – namely, whether to regulate and, if so, exactly how to do so.

To understand problems and their potential solutions, regulatory decision making depends on science in several ways. By science, I mean, in general terms, systematic inquiry aimed at generating evidence about and explanations of how the world operates.[3] Science is needed, first, to measure, track, and explain the cause of problems -- although importantly it does not tell us why something is properly considered a problem in the first place. Second, by helping understand what causes a problem, science may help inform the process of generating ideas about possible solutions – namely interventions that address different causal pathways to the problem. Finally, science can also quite usefully inform assessments of how different solutions will fare in terms of at least certain types of policy criteria. For example, scientific knowledge about swine flu viruses is clearly essential in assessing the effectiveness in preventing disease transmission of alternative solutions like washing hands versus avoiding pork products.

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[2] For treatments of policy decision making, see David Weimer & Aidan R. Vining, *Policy Analysis: Concepts and Practice* (4th ed. 2004), and Eugene Bardach, *A Practical Guide for Policy Analysis: The Eightfold Path to More Effective Problem Solving* (2008).

[3] The Supreme Court has defined science as ""a process for proposing and refining theoretical explanations about the world." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 590 (1993).

Science cannot, though, tell a regulator which criteria should be used to evaluate possible alternatives, nor how to balance or make trade-offs between different criteria, whether effectiveness, efficiency, equity, or other policy considerations. Science also cannot make or direct the ultimate choice about what solution should be selected from the alternatives considered. The ultimate choice of whether, how, and how stringently to regulate is a normative or policy judgment: "Science describes; it does not prescribe."[4]

Regulators may sometimes be justified to take action before scientists can conclude that they understand well a problem's causes or can predict with a high degree of confidence how all possible solutions might fare. At other times, scientists may be able to specify the contours surrounding a problem with a great deal of confidence, but regulators may nevertheless be justified to allow that problem to persist – if other weightier (or at least equally weighty) policy considerations so dictate. Solving one problem could, after all, only create other problems. In the context of regulatory policy, science's role – or what President Barack Obama in his Inauguration Address called its "rightful place" – is to provide a *necessary but not sufficient* input into policy decisions.

Members of the scientific community have long emphasized the need to clarify the role science can and cannot play. As early as 1983, in its well-known *Red Book* report, the National Research Council (NRC) called for maintaining a clear conceptual distinction between scientific judgments and policy judgments in risk regulation. The NRC distinguished between risk *assessment*, which it considered to encompass predominantly scientific analysis, and risk *management*, which it said entails consideration of "political, social, economic, and engineering information…to select the

[4] Cary Coglianese & Gary Marchant, "Shifting Sands: The Limits of Science in Setting Risk Standards," *University of Pennsylvania Law Review* 152: 1255, 1274 (2004).

appropriate regulatory response."[5] In another report issued in 1996, the NRC explained still more bluntly that "science alone can never be an adequate basis for a risk decision" because such "decisions are, ultimately, public policy choices."[6]

Regulatory agencies have not always acknowledged that their decisions are ultimately policy choices, albeit ones informed by science. Legal scholar Wendy Wagner has characterized as pervasive a practice she has called the "science charade," with regulators confronting "multiple political, legal, and institutional incentives to cloak policy judgments in the garb of science."[7] Professor Gary Marchant and I have chronicled in detail one such charade undertaken by the U.S. Environmental Protection Agency (EPA), when it amended its major ambient air quality standards for ozone and particulate matter in the late 1990s.[8] In explaining its amendments, the EPA Administrator at the time made repeated claims to the effect that "science must prevail in determining the level of protection the public will be guaranteed."[9] When the EPA revised its particulate standard nearly a decade later, in 2006, the agency again exaggerated the role of science, arguing that it "based this decision on an assessment of a significantly expanded body of scientific information" and "[t]he assessment concluded

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[5] National Research Council, National Academy of Sciences, *Risk Assessment in the Federal Government: Managing the Process* 18-19 (1983).
[6] National Research Council, *Understanding Risk: Informing Decisions in a Democratic Society* 26 (1996).
[7] Wendy E. Wagner, "The Science Charade in Toxic Risk Regulation," *Columbia Law Review* 95: 1613, 1650-51 (1995). *See also* Thomas O. McGarity & Wendy E. Wagner, *Bending Science: How Special Interests Corrupt Public Health Research* 21 (2008) ("In today's legal climate, science has become the most respected and therefore the most powerful influence on domestic health and environmental policy-making.").
[8] Coglianese & Marchant, *supra* note 4.
[9] *Id*. at 1273 (quoting then-Administrator Carol Browner).

that the standard should be strengthened."[10] Yet science is about understanding or predicting what *is*, not about concluding or justifying what a standard *should* be.

Policy decisions can be based on a variety of principles. For example, in the realm of environmental or health and safety regulation, agencies can set standards that seek to: (1) eliminate all unacceptable risks (the acceptable risk principle), (2) eliminate risk until the costs of doing so reach an unacceptable level (the feasibility principle), or (3) balance the benefits and costs of risk reduction (the efficiency or cost-benefit principle). Each of these principles deserves their own justification.[11] But the point here is that despite the availability of these and other policy principles, regulatory agencies like EPA face incentives and constraints that at times lead them to retreat behind a false veil of science.

One such constraint takes the form of authorizing statutes that preclude or discourage agencies from relying on meaningful policy principles. For example, the courts and EPA have interpreted Section 109 of the Clean Air Act to prevent the agency from considering costs in setting ambient air quality standards -- so instead the agency purports to rely on science to set a standard at a level that is "not lower or higher than is necessary" to protect public health.[12] EPA must cloak its air quality standard-setting in the "garb of science," without being able to provide a coherent policy justification for

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[10] EPA, Fact Sheet Final Revisions to the National Ambient Air Quality Standards For Particle Pollution (Particulate Matter), http://www.epa.gov/air/particlepollution/pdfs/20060921_factsheet.pdf (Sept. 21, 2006) (last accesses 4/28/09).

[11] For a discussion of rationales for, and some limitations of, these various principles, see Coglianese & Marchant, *supra* note 4, at 1325-1340. Professors Matthew Adler and Eric Posner have offered a recent book-length justification of the cost-benefit principle. Matthew D. Adler & Eric A. Posner's *New Foundations of Cost–Benefit Analysis* (2006). For a recent exchange about their book, see Amy Sinden, Douglas A. Kysar, and David Driesen, "Cost-Benefit Analysis: New Foundations on Shifting Sand," *Regulation & Governance* 3:48 (2009), and Matthew Adler & Eric A. Posner, "New Foundations of Cost-Benefit Analysis: A Reply to Professors Sinden, Kysar, and Driesen," *Regulation & Governance* 3:72 (2009).

[12] *Whitman v. American Trucking Association, Inc.*, 531 U.S. 457 (2001).

why it selects particular standards at the levels it does (and not at levels lower or higher).[13]

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. For example, when EPA rejected the most stringent proposed standards in its ozone and particulate rulemakings, citizens never received an adequate policy explanation for why the agency effectively decided to tolerate some residual, known health effects. Nor did citizens receive a coherent policy reason for why, in rejecting the least stringent option, the agency effectively accepted potential job losses or increases in citizens' utility bills owing to compliance costs.[14]

In addition to detracting from transparency and accountability, when agencies exaggerate the role of science they may create other perverse effects. Wendy Wagner and Rena Steinzor have suggested that "[t]he more emphasis that regulators place on science, the greater the affected parties' incentives to do what they can to control its content and production" – which on Wagner and Steinzor's account includes the veritable harassment of independent scientists by organized interests that do not like the scientists' findings.[15] More globally, in terms of public policy outcomes, if agencies avoid confronting the policy choices inherent in making regulation, they may be much more likely to make inconsistent or suboptimal decisions.[16]

Legislators have options to consider that could reduce agencies' incentives to retreat behind science. Congress could reconsider and rewrite statutory provisions that

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[13] Coglianese & Marchant, *supra* note 4.
[14] *Id*. at 1355-56.
[15] Wendy Wagner & Rena Steinzor, *Rescuing Science from Politics: Regulation and the Distortion of Scientific Research* 4 (2006).
[16] *See* Coglianese & Marchant, *supra* note 4, at 1290-1323.

the courts have construed in a way that effectively forces agencies into misrepresenting the role of science, such as with Section 109 of the Clean Air Act. It could consider options for enhancing oversight of policy reasoning by the White House Office of Information and Regulatory Affairs or the courts, or it could impose requirements or make requests of its own that agencies clearly demarcate the role science has played in their decisions and the role played by policy reasoning.

Many observers of the regulatory process have properly sought to enhance "sound science" in agency decision making – or to avoid what is variously considered "junk science"[17] or "bent science."[18] But just as there is always room for improving the quality of the science that regulatory agencies must necessarily and properly rely upon, there are also opportunities to enhance the quality of agencies' policy reasoning, especially in those instances where they misleadingly suggest that science has determined their decisions.

[17] Peter Huber, *Galileo's Revenge: Junk Science in the Courtroom* (1991).
[18] McGarity & Wagner, *supra* note 7.