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President
Regulatory Checkbook

Hearing on

Fostering Quality Science at EPA:
Perspectives on Common Sense Reforms—Day II

Before

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Committee on Science, Space, and Technology U.S. House of Representatives

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REGULATORY CHECKBOOK

INTRODUCTION

Chairman Harris, Ranking Member Miller, and Members of the Subcommittee, thank you for inviting me to testify on "Fostering Quality Science at EPA: Perspectives on Common Sense Reforms." I am Dr. Richard B. Belzer, president of Regulatory Checkbook, a nonpartisan nonprofit organization whose mission includes the promotion of quality improvements in science, economics, and information quality.[1]

I was elected Treasurer of the Society for Risk Analysis in 1998 and 2000, and earned its Outstanding Service Award in 2003. Previously I was named a Fellow of the Cecil and Ida Green Center for the Study of Science and Society. In 2009 and 2011, I was elected Secretary/Treasurer of a new professional organization, the Society for Benefit-Cost Analysis.

From 1988 through 1998, I was a career economist in OMB's Office of Information and Regulatory Affairs, where I reviewed many risk assessments that were integral parts of agencies' Regulatory Impact Analyses, for it is impossible to estimate costs and benefits without first estimating risks. My job was to examine agency analyses of the risks, costs, and benefits of draft regulations, and present to OMB officials and other Executive Office staff the most objective portrayal possible. Typically, this could not be done based on the risk assessments performed by the agencies. Agency risk assessments were purposefully biased to make risk appear greater than it was and the benefits of regulation appear greater than they were.

I have been president of Regulatory Checkbook since its founding in 2001. Regulatory Checkbook does not lobby or take public positions on substantive legislation or rule making; there is no shortage of organizations committed to doing that. Our sparsely populated niche is to seek improvements in the quality of risk assessment and economic analysis regardless of whether it tends to support or oppose specific regulatory actions. For that reason, we are interested in how quality as affected by various procedures, such as public comment, peer review, information quality principles and

[1] The views expressed here are my own and do not necessarily represent those of Regulatory Checkbook.

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standards, and Executive oversight. No one has compensated Regulatory Checkbook or me for my testimony.

I am familiar with testimony previously provided to the Subcommittee. I will try to build on that and not be redundant.

SYMPTOMS OF THE QUALITY DEFICIT

The purpose of these hearings has been to identify ways to improve the quality of science used by EPA in regulatory decision-making. This, of course, implies that the state of the science for science at the Agency is not well. Numerous symptoms have been identified.

Politicization of science or scientization of policy?

In March 2009, President Obama issued a Memorandum on Scientific Integrity stating, among other things, "Political officials should not suppress or alter scientific or technological findings and conclusions."[2] The President also made a commitment to transparency, saying, "If scientific and technological information is developed and used by the Federal Government, it should ordinarily be made available to the public." It is my observation, based on over 20 years in risk assessment, that these principles are are universally agreed to—in principle. Putting them into policy turns out to be more difficult. It took 22 months for the White House Office of Science and Technology Policy—an office whose director the President directly supervises—to issue guidance implementing his memorandum.[3]

Moreover, OSTP's guidance is crafted with considerable structural and procedural ambiguity.[4] It calls for "policymakers [to] involve science and technology experts where appropriate," without clearly stating the circumstances where it wouldn't be. It directs agencies to select candidates for scientific positions "based primarily

[2] Barack Obama. "Scientific Integrity." Federal Register, 2009, 74(46), 10671-10672.

[3] John P. Holdren. "Memorandum for the Heads of Executive Departments and Agencies: Scientific Integrity," Office of Science and Technoloy Policy, 2010.

[4] OSTP's guidance is mostly hortatory, saying agencies "should" do various things 19 times but never saying "shall" or "must." Eight times, these suggestions apply only if the agency judges them to be "appropriate." Four times, they apply only if "practicable."

on their scientific and technological knowledge, credentials, experience, and integrity," thereby leaving wide open the option of giving substantial weight to their political affiliation or policy views.[5] It calls for "independent peer review by qualified experts," but only "where feasible and appropriate." The guidance says "political officials should not suppress or alter scientific or technological findings," but it does not actually generally prohibit this practice.[6] Only agency public affairs officers are expressly forbidden from doing this.[7]

The lesson from this is that it is much easier to announce a policy that seems straightforward than to implement it. It turns out that the intersection of policy and science is a lot more complicated than newspaper reporters, activists, and even candidates for president might think.

As the Subcommittee has heard, the 2009 report of the Bipartisan Policy Center's Science Policy Project discreetly pointed in a different direction—what is increasingly being called "the scientization of policy."[8] The BPC's Science Policy Project included former policy officials who, unsurprisingly, had a different perspective on the policy/science divide. Former OIRA Administrator Susan Dudley's testimony to the Subcommittee appears to be indicative of this, presumably reflecting her own experience.[9]

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[5] President Obama's memorandum did not include this qualification, stating: "The selection of scientists and technology professionals for positions in the executive branch should be based on their scientific and technological knowledge, credentials, experience, and integrity."

[6] The President's memorandum went further, saying "Political officials should not suppress or alter scientific or technological findings and conclusions" (emphasis added). The difference is surely not accidental, but its significance is not transparent. Possibly it shows that the White House has learned about the scientization of policy.

[7] Holdren (2010, p. 2). "In no circumstance may public affairs officers ask or direct Federal scientists to alter scientific findings."

[8] Bipartisan Policy Center. "Improving the Use of Science in Regulatory Policy," Washington, D.C.: Bipartisan Policy Center, 2009, p. 15. "[S]ome disputes over the 'politicization' of science actually arise over differences about policy choices that science can inform, but not determine."

[9] Susan E. Dudley. "Written Testimony Before the U.S. House of Representatives Committee on Science, Space, and Technology, Subcommittee on Energy and the Environment, Hearing on 'Fostering Quality Science at EPA: Perspectives on Common Sense Reforms'," 2011.

It turns out that this is an old issue. In 1986, Harvard Kennedy School professors Albert Nichols and Richard Zeckhauser published papers claiming that cancer risk was systematically overstated at EPA.[10] They wrote that this was done by Agency risk assessors for the purpose of influencing risk management decisions.[11]

In 1990, the Office of Management and Budget elaborated upon this problem in its *Regulatory Program of the United States Government*:

> *Unfortunately, risk-assessment practices continue to rely on conservative models and assumptions that effectively intermingle important policy judgments within the scientific assessment of risk. Policymakers must make decisions based on risk assessments in which scientific findings cannot be readily differentiated from embedded policy judgments. This policy environment makes it difficult to discern serious hazards from trivial ones, and distorts the ordering of the Government's regulatory priorities. In some cases, the distortion of priorities may actually increase health and safety risks.* [12]

OMB noted with approval the recommendation made by the committee that wrote the National Research Council's 1983 *Red Book*:

> *Regulatory agencies should take steps to establish and maintain a clear conceptual distinction between assessment*

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[10] Albert L. Nichols and Richard J. Zeckhauser. "The Dangers of Caution: Conservatism in Assessment and the Mismanagement of Risk," Smith, Advances in Applied Micro-Economics: Risk, Uncertainty, and the Valuation of Benefits and Costs. Greenwich, Conn.: JAI Press, 1986a, 55-82. For a less technical version of this paper, see _____. "The Perils of Prudence: How Conservative Risk Assessments Distort Regulation." Regulation, 1986b, 10(6), 13-24.

[11] It is not clear, however, if this practice illustrates the scientization of policy, or the politicization of science by Agency staff rather than by Agency policy officials. It may have elements of both.

[12] Office of Management and Budget. "Current Regulatory Issues in Risk Assessment and Risk Management," Regulatory Program of the United States, April 1, 1990 -- March 31, 1991. Washington, DC: Office of Management and Budget, 1990, 13-26. Full disclosure: I was the author of OMB's white paper. It is out of print but available on my web site at http://www.rbbelzer.com/uploads/7/1/7/4/7174353/omb_1990_risk_assessment.pdf .

> *of risks and the consideration of risk management alternatives; that is, the scientific findings and policy judgments embodied in risk assessments should be explicitly distinguished from the political, economic, and technical considerations that influence the design and choice of regulatory strategies.*[13]

Like the authors of the *Red Book*, OMB thought that fidelity to the *Red Book* recommendations was at least part of the solution. Though it was published more than 20 years ago, the problem OMB highlighted is the same thing that the BPC identified.[14]

While this is an old story, that does not mean it is outdated. In 2004, EPA published a staff report that explains its risk assessment policies and practices with signal clarity. This report acknowledges that EPA risk assessments are intentionally biased to overstate risk, and that this is done for the purpose of scientizing policy:

> *[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.* [15]

All risk assessments err because they are estimates. What the EPA staff said is that they have a strong preference for erring on the side of overestimating risk, just not "grossly" overestimating it. They justify this preference based on the "health and environmental mission" of the Agency. This preference for overestimating the magnitude of risk is in addition to a preference for erring on the side of promulgating regulations that err on the side of overprotection.

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[13] National Research Council. Risk Assessment in the Federal Government: Managing the Process. Washington, D.C.: National Academies Press, 1983, p. 151.

[14] Bipartisan Policy Center (2009, p. 13). "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 differences about policy choices that science can inform, but not determine" (p. 13).

[15] U.S. Environmental Protection Agency Office of the Science Advisor. "An Examination of EPA Risk Assessment Principles and Practices; Staff Paper, EPA/100/B-04/001," 2004, p. 13. This does not necessarily mean that EPA always succeeds in overstating risk, or that there are not circumstances in which EPA does not understate risks, whether by accident or intent.

It is worth reflecting on what this would mean if other Federal agencies did the same thing:

- Would it be reasonable for engineers at the Federal Aviation Administration to intentionally overestimate the risk of air travel, perhaps by assuming all aircraft were as risky as the riskiest of them, and use those overestimates to motivate the FAA Administrator to promulgate more stringent safety regulations for all aircraft?
- Would it be reasonable for examiners in the Department of the Treasury to knowingly overstate the risk that a major bank might fail, in order to persuade the Secretary to take over that bank?
- Would it be reasonable for analysts at the Central Intelligence Agency to purposefully overstate the likelihood that the Islamic Republic of Iran will succeed in developing an fielding a nuclear weapon, thereby encouraging the President to launch a preemptive military attack?

To ask these questions is to answer them. It is the obligation of Federal risk assessors, no matter where they work, to estimate risk as objectively as possible. They should never misuse the tools of risk assessment to manipulate decision makers into taking specific actions. Remarkably, the EPA staff report denies that the discretion of Agency policy officials is constrained or misdirected by their practice of purposefully overestimating risk.[16]

DIAGNOSIS

Whether science has been politicized or policy has been scientized is a useful distinction, but it is not complete. For example, it is assumed that science is politicized when policy officials invade the space of the scientists; and conversely, policy is scientized when agency scientists attempt to make policy decisions that Congress has delegated to agency heads.

This model is incomplete because Agency policy officials and risk assessors appear equally prone to do both. Sometimes, it is agency

[16] U.S. Environmental Protection Agency Office of the Science Advisor (2004, pp. 14-16).

policy officials who scientize policy, such as when they try to attribute their policy choices to science. A policy official can avoid a lot of controversy if he is perceived as "merely following the science."[17]

Agency risk assessors may be willing or even pleased to go along, for it increases their power and authority inside the agency, in its battles with OMB, and for deflecting Congressional criticism. Thus, Agency risk assessors may have no more interest than Agency policy officials in revealing the extent to which officials have attributed policy decisions to science. Similarly, Agency officials and risk assessors alike may prefer not to make transparent the extent to which risk assessors actually make policy decisions under the cover of science.

Conflict arises, however, when Agency officials and risk assessors do not agree on policy. In these situations, Agency policy officials must first reclaim from Agency risk assessors the authority delegated to them by Congress to make policy decisions. It is easy for risk assessors to accuse their political bosses of politicizing science and nearly impossible for policy officials to defend themselves when the charge is false.

On the other hand, sometimes it is Agency risk assessors who politicize science. This happens when risk assessors choose the best available science that supports their preferred policy decision. Few policy officials would ever be the wiser because it requires from them independent scientific expertise, substantial issue-specific knowledge, and more time than they have available.

The desired principles can be clearly expressed, if not easily implemented:

- Agency policy officials should be limited to making policy.
- Agency risk assessors should be limited to assessing risk.

[17] In previous testimony to this Subcommittee, EPA Administrator Jackson's decision to revise the 2008 National Ambient Air Quality Standard for ozone following the recommendations of the Clean Air Scientific Advisory Committee was described by a former CASAC chairman in similar but more strident terms. See Roger O. McClellan. "Written Testimony Before the U.S. House of Representatives, Committee on Science, Space, and Technology, Subcommittee on Energy and the Environment, Hearing on 'Quality Science for Quality Air'," 2011.

- Risk assessment should be performed as objectively as possible, and not be misused as a tool for achieving policy objectives through the back door.

Policy officials should stay out of science. They should allow science to inform their decisions but never allow it to control them, never hide behind it, and never tell scientists what conclusions to reach. They also should be persistent about asking risk assessors the right questions, and getting second opinions from external authorities.

This goal begins with the *Red Book* recommendation and goes much further. Whereas the *Red Book* authors envisioned a smoothly interactive and iterative relationship between risk assessors and risk managers, with a "clear conceptual distinction" between science and policy "established and maintained," 30 years of history has shown that this model has either failed or cannot be implemented in a real-world regulatory agency.[18]

In the following sections I focus on three areas in which EPA science has specific, notable deficiencies. These are information quality, peer review, and the confused role of Federally chartered advisory groups.

[18] The author of this recommendation on behalf of the *Red Book* committee believes that EPA officials misinterpreted and misapplied it. See D. Warner North. "Reflections on the Red/Mis-Read Book, 20 Years After." Journal of Human and Ecological Risk Assessment, 2003, 9(5), 1145-1154. An somewhat different interpretation is that implementation as envisioned by the Committee was not administratively or politically feasible, an interpretation Professor Marchant appears to favor. See Gary E. Marchant. "Written Testimony Before the U.S. House of Representatives Committee on Science, Space, and Technology, Subcommittee on Energy and the Environment, Hearing on 'Fostering Quality Science at EPA: Perspectives on Common Sense Reform'," 2011, p. 5. "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." Marchant does not credibly explain how an external science production entity, such as his proposed Institute for Scientific Assessments, staffed and managed by full-time Federal employees, would not succumb to the twin temptations of politicization and scientization.

Information quality principles and standards

In 2002, OMB issued government-wide guidelines[19] to implement a statutory directive to improve information quality.[20] Like almost every other covered agency, EPA issued its own agency-specific guidelines before the October 1, 2002 deadline.[21] These guidelines commit EPA to adhere to certain standards of transparency, reproducibility, integrity, objectivity, and utility, and to establish administrative mechanisms whereby any person may seek and obtain the correction of noncompliant information. Indeed, EPA expressed the view that adhering to OMB's guidelines would not pose any challenge because its existing policies and procedures already ensured and maximized information quality.[22]

EPA's information quality guidelines say the Agency "is dedicated to the collection, generation, and dissemination of high quality information" and "seeks to foster the continuous improvement of existing information quality activities and programs." "In implementing these guidelines," EPA said "ensuring the quality of information is a key objective alongside other EPA objectives, such as ensuring the success of Agency missions, observing budget and resource priorities and restraints, and providing useful information to the public."[23] EPA also established well-defined administrative procedures for managing requests for correction and administrative appeals.

To be clear, information quality standards are expansive. They apply to "any communication or representation of knowledge such as facts or data, in any medium or form"— but not to policy decisions. Thus, they apply to risk assessment documents to the extent that they contain "representation[s] of knowledge such as facts or data." Because EPA officials claim that Agency risk assessment products are

[19] Office of Management and Budget. "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Notice; Republication." Federal Register, 2002, 67(36), 8452-8460.

[20] "Information Quality Act." 44 U.S.C. 3516 note. 2000.

[21] U.S. Environmental Protection Agency. "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency (EPA/260R-02-008)," 2002.

[22] U.S. Environmental Protection Agency (2002, pp. 10-14).

[23] U.S. Environmental Protection Agency (2002, p. 10).

scientific,[24] there is no doubt that they are fully covered by applicable information quality guidelines.

The Subcommittee should be aware that EPA has exempted press releases and fact sheets from its information quality guidelines, which it describes as "[i]nformation of an ephemeral nature." Given that press releases and fact sheets are often the only information Congress and the press know about a complex risk issue, this exemption is obviously problematic. Further, the Subcommittee should be aware that EPA also exempts "[i]nformation presented to Congress as part of the legislative or oversight processes."[25] EPA testimony may have many desirable attributes, but adherence to information quality principles and standards is not one of them.

Many error correction requests submitted to EPA concern Agency risk assessments or components thereof, which the petitioner claims, contain factual errors. Some requests are intended to seek full disclosure of data and methods to enable third parties to test for error, which both OMB's and EPA's information quality guidelines require.[26]

EPA committed to respond to requests for correction and appeals within 90 days. EPA's actual performance, however, has not lived up to these commitments. As of September 30, 2010, EPA's average response time for a request for correction was no less than 166 days. EPA's average response time for an appeal was no less than 316 days.[27] These figures are biased downward, and thus understate EPA's

[24] Paul Anastas. "Written Testimony Before the U.S. House of Representatives Committee on Science Space and Technology, Subcommittee on Oversight, Hearing on 'EPA's Integrated Risk Information System'," 2011, p. 1. "IRIS assessments provide a scientific foundation for EPA decisions to protect public health across EPA's programs and regions under an array of environmental laws" (emphasis added).

[25] U.S. Environmental Protection Agency (2002, pp. 16-17).

[26] Some requests for correction are misguided attempts to change regulatory decisions. However, these requests are easy for EPA to dismiss on the ground that they concern matters that are exempt from the information quality paradigm.

[27] Richard B. Belzer. "Risk Assessment and Information Quality: An Empirical Study of Federal Agency Performance, 2010 Update," Society for Risk Analysis 2010 Annual Meeting, Salt Lake City, Ut., 2010. Since this paper was presented, EPA has received four new requests for correction.

dilatory behavior, because they include requests and appeals that were still open at the end of FY 2010.[28]

In short, EPA's well-written administrative procedures have in practice failed to enable affected persons to "seek and obtain" the correction of information that does not comply with applicable information quality principles. Assuming it takes only 45 days to review EPA's response to a request for correction and file an appeal, it has taken on average more than 527 days for EPA's internal administrative process to run its course.

The substantive merits of these requests for correction vary, but it cannot be denied that many are highly meritorious. This can be seen by reviewing specific requests or logically inferred by the length of time EPA takes to respond. It should be easy for the Agency to quickly refute requests for correction that lack any merit, especially those which impermissibly seek to challenge Agency policy decisions. Conversely, requests for correction that are highly meritorious could be very hard to refute. If acknowledging error would undermine the legal standing or political legitimacy of a major regulation or an important EPA policy, no one should be surprised that the Agency takes a long time to decide how to respond, or that its responses are ambiguous, technically weak, misleading, or flatly wrong.

If an agency's response to a request for correction is incomplete, misguided, or lacks merit, the only recourse is an appeal within the agency. One cannot appeal to another Executive branch agency or seek review by a Federal court. For that reason, public enthusiasm is limited even for submitting the most meritorious of error correction requests. Government-wide, the number of requests for correction filed annually has declined by more than 75% since FY 2003. This is not because Federal agencies have suddenly stopped disseminating erroneous information. It is because the agencies have responded to the Information Quality Act as if it were a potentially lethal virus and developed effective antibodies to prevent reinfection.

[28] Eleven of 44 requests for correction and one of 16 appeals remained open at the end of FY 2010. The average response time, once these open actions were resolved, could only be greater.

Peer Review

EPA is perhaps the Federal agency that has committed the most to peer review. It conducts numerous peer reviews every year and has published a series of handbooks that guide Agency staff through the process.[29] Nevertheless, there appears to be widespread dissatisfaction with the actual performance of EPA peer review. This is self-evident given Congress' repeated decisions to supplement or even bypass EPA peer review in favor of the National Academy of Sciences.

Several problems afflicting EPA's peer review program are discussed below.

OMB's *Bulletin on Peer Review* contains obvious errors

OMB issued government-wide guidance on peer review in 2005.[30] This guidance is generally very useful and helpful. For example, it clearly states, "Peer reviewers shall be charged with reviewing scientific and technical matters, leaving policy determinations for the agency."

But OMB's guidance is especially weak exactly where it should have been strongest. Even though enhancing information quality was its *raison d'être*, the guidance includes no requirement that agencies actually make information quality principles and standards an integral part of scientific peer review. OMB waffles, saying "[r]eviewers shall be informed of applicable access, objectivity, reproducibility and other quality standards under the Federal laws governing information access and quality."[31] In short, an EPA peer review complies with OMB's guidance as long as peer reviewers are informed about information quality, perhaps similar to one of the dozens of disclosure forms that must be provided at settlement when purchasing a house. There is no obligation for peer reviewers to do anything with this information.

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[29] U.S. Environmental Protection Agency. "Peer Review Handbook (1st Ed.)," Washington, D.C.: U.S. Environmental Protection Agency Science Policy Council, 1988, _____. "Peer Review Handbook (2d Ed.)," Washington, D.C.: U.S. Environmental Protection Agency Science Policy Council, 2000, _____. "Peer Review Handbook (3rd Ed.)," Washington, D.C.: U.S. Environmental Protection Agency Science Policy Council, 2006.

[30] Office of Management and Budget. "Final Information Quality Bulletin for Peer Review." Federal Register, 2005, 70(10), 2664-2667.

[31] Office of Management and Budget (2005, p. 2675). Emphasis added.

OMB's guidance also includes a pair of extraordinarily large loopholes. First, OMB allows agencies to infer that studies published in peer-reviewed literature adhere to information quality principles and standards, including the crucial standards of presentational and substantive objectivity. This is bizarre. Adherence to these principles plays no role in journal review. If they knew about them, some editors of scholarly journals probably would consider information quality principles and standards wholly irrelevant or contradictory to the journal's mission. No matter; to OMB, peer review by a scholarly journal means the information contained in it is presentationally and substantively objective.

Second, OMB exempts reports of the National Academy of Sciences from any scrutiny whatsoever.[32] This is true even if there is no evidence that the review took account of applicable information quality principles and standards, or there is incontrovertible evidence that the review violated these principles and standards.[33]

Information quality is AWOL from EPA peer review

EPA's latest Peer Review Handbook mentions information quality several places, but each reference is little more than boilerplate. Here is the most substantive reference I can find:

> *The Agency recognizes peer review as a component of pre-dissemination review that complements and enhances the "objectivity" and "utility" of EPA's information products. The Agency recommends that offices conduct pre-dissemination reviews of information to ensure that the information is of appropriate quality before it is disseminated to the public. Pre-dissemination review is especially important for influential scientific information and highly influential scientific assessments.*[34]

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[32] Office of Management and Budget (2005, p. 2675). "Principal findings, conclusions and recommendations in official reports of the National Academy of Sciences are generally presumed to have been adequately peer reviewed." OMB may have tried to hedge this blanket endorsement by limiting it to "principal findings," but the effectiveness of this hedge seems likely to be ephemeral.

[33] An incontrovertible violation would occur in any instance where the Academy gives policy advice. See the discussion surrounding footnote 30.

[34] U.S. Environmental Protection Agency (2006, p. 17).

Notice that pre-dissemination review, which applicable information quality guidelines require agencies to perform, is reduced to a mere recommendation. The Handbook does not even include OMB's requirement that peer reviewers be "informed" about information quality principles and practices, so it should surprise no one when they aren't.

A reasonable inference is that EPA's Science Policy Council, the author of the Peer Review Handbook, does not want information quality to play a meaningful role in Agency peer review. Rather, the SPC hopes that by conducting peer review EPA will be treated as if it had complied with information quality principles and standards. This is wholly unjustified. Peer reviews conducted fully in compliance with the letter of the Handbook do not and cannot adhere to information quality principles and standards because those principles and standards are AWOL.

EPA's Science Advisory Board and the National Academy of Sciences are not solutions to this problem, for their reviews are no more likely to take information quality seriously. To take one obvious example, many observers have strongly endorsed Chapter 7 of the Academy's review of EPA's draft assessment of formaldehyde as a highly desirable step forward for improving the quality of IRIS assessments.[35] Perhaps it is, but the Academy's formaldehyde report does not include adherence to information quality principles and standards anywhere in its "road map." Indeed, the report never even mentions information quality, which suggests that the formaldehyde committee was utterly unaware of EPA's information quality guidelines.[36]

For this reason, the Chapter 7 "road map" might not be as helpful as its advocates hope. Most disturbingly, any Congressional

[35] National Research Council. Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde. Washington, D.C.: National Academies Press, 2011.

[36] This does not mean the formaldehyde committee ignored information quality in its review. Several places in the report one can find discussions that indicate the committee wrestled with quality issues. Similarly, the "road map" has numerous references to "quality" because it wanted EPA to focus on "high quality" studies. But the committee was bereft of a framework for defining quality because it apparently knew nothing about EPA's Information Quality Guidelines.

directive to EPA insisting that it adhere to the "road map" is an implicit invitation for the Agency to ignore information quality. Surely Congress did not intend this to happen.

Noncompliance with the Peer Review Handbook

There are numerous anecdotes suggesting that EPA peer reviews do not actually comply with the Peer Review Handbook. I am unaware of any systematic research on this question that would permit a more comprehensive inference. Clearly, such research could be valuable if it were conducted rigorously and independently of EPA.

Obviously, if research showed that EPA's adherence the Peer Review Handbook was as spotty as is the Agency's adherence to its information quality guidelines, this might go a long way toward explaining why there appears to be such widespread dissatisfaction with EPA peer review. Research also could discover if noncompliance with the handbook was random or causally associated with specific issues or regulatory programs.[37]

Excessive Agency control

EPA's Peer Review Handbook makes clear that the Agency retains full control over the peer review charge and de facto control over the selection of peer reviewers. This is obviously true when a peer review is conducted by a panel established by EPA under the Federal Advisory Committee Act (FACA). But it is also true when the EPA conducts a workshop or contracts with a private company to conduct peer review. In these circumstances, EPA still controls the charge[38] and has the authority to veto the contractor's selection of peer reviewers.[39]

Nonscientific content in EPA's charge to scientific peer reviewers

[37] It is an open question whether this question is researchable. "Compliance" with a complex guidance document is not a binary state. The research task would involve a painstaking review of a representative sample of peer reviews. The sample would have to be large enough to have the statistical power to reject the null hypothesis.

[38] U.S. Environmental Protection Agency (2006, p. 59).

[39] U.S. Environmental Protection Agency (2006, p. 61).

EPA peer review panels often are given a charge that includes crucial nonscientific content for which scientists have no special skills or insights. This occurs, for example, when a peer review panel is constrained to look at scientific information through the Agency's policy lenses. Common examples include the derivation of unit risk factors for carcinogens and Reference Doses for noncarcinogens, both of which have scientific content but are controlled by policy choices. When a scientific peer review panel is asked to review a proposed unit risk factor or Reference Dose, it is being asked to ratify the Agency's policy choices.

Insufficient expertise

By virtue of their size, peer review panels may appear to be capable of reviewing all the relevant scientific questions posed by a draft risk assessment. This may not be true, however, if the issues presented are very broad and cross multiple disciplines. On a panel containing the 15 best external scientists, there may be just a couple who have crucial expertise related to a specific issue. If the number of scientific issues is large, reviewers will be assigned to those issues on which then have the most expertise. When it comes time to put the review together, panel members will be inclined to jealously guard the portion of the review they performed but defer completely to other members with respect to the rest. Instead of a single peer review performed by a panel of 15, the final report may be a half-dozen or more separate reviews, each performed by a small number of scientists, then repackaged as is it were a single document.

Excessive expertise, of a certain form

It is becoming increasingly common to observe a peer review panel consisting of experts who are the authors of the research on which EPA has based its risk assessment. These experts are valuable and important, for they alone can ensure that the Agency has interpreted their work correctly. But they have no business serving on a peer review panel whose job will be to review whether these studies were performed correctly, whether they are the best available, whether they are objective, etc.

This practice is disturbingly commonplace. The Clean Air Scientific Advisory Committee (CASAC), which performs a peer review

function under Section 109(d)(2) of the Clean Air Act, is chaired by an author of studies on which EPA bases risk assessments for mortality caused by ambient air pollutants.[40] Four of the seven current members of CASAC have published research referenced in EPA's latest Integrated Science Assessment for ozone, which CASAC is responsible for reviewing. A scientist who formerly served on CASAC has testified before this Subcommittee that he was also a contributing author of multiple ISAs.[41] It is simply impossible for CASAC to independently peer review EPA risk assessment documents that rely on its members' own research. In fact, it violates EPA's Peer Review Handbook, for it represents the ultimate conflict of interest.[42]

Conflicts of interest

Most observers seem to agree that conflicts of interest ought to be avoided if at all possible, and that peer review panels should manage bias by ensuring that a "balance of biases" is obtained. This principle is key to the National Academy's model, for example.[43]

I unapologetically take a different view.[44] We are saddled with conflict-of-interest policies that were written by lawyers in a way that

[40] M.L. Bell, F. Dominici and J.M. Samet. "A meta-analysis of time-series studies of ozone and mortality with comparison to the national morbidity, mortality, and air pollution study." Epidemiology, 2005, 16(4), Michelle L. Bell, Aidan McDermott, Scott L. Zeger, Jonathan M. Samet and Francesca Dominici. "Ozone and Short-term Mortality in 95 US Urban Communities, 1987-2000." JAMA, 2004, 292(19), 2372-2378.

[41] George D. Thurston. "Written Testimony Before the U.S. House of Representatives, Committee on Science, Space, and Technology, Subcommittee on Energy and the Environment, Hearing on 'Quality Science for Quality Air': *RE: The Science of Air Pollution Health Effects and The Role of CASAC in EPA Standard Setting*," 2011, p. 2.

[42] U.S. Environmental Protection Agency (2006, p. 37). "Since it would probably result in a perceived, if not real, conflict of interest, the group that is generating the work product usually cannot conduct or perform the peer review of its own work product."

[43] The National Academies. "Policy on Committee Composition and Balance and Conflict of Interest," The National Academies, 2003.

[44] A more extensive discussion of the contrasts between scholarly and governmental peer review can be found in a paper I wrote for a 2002 conference sponsored by the Society for Risk Analysis. See Richard B. Belzer. "Interests and Incentives in Government Peer Review," Conflict, Consensus, and Credibility: A

makes them easy for lawyers to implement.[45] They treat appearances the same as facts, and minor financial interests related to for-profit employment more gravely than huge financial interests related to dependence on government research grants. Conflict of interest policies include measures to balance bias because scientific peer review panels routinely do more than review science—they opine on policy.

Public participation is limited and public comments are ignored

EPA's Peer Review Handbook purports to welcome public participation in peer review, but it treats the public as a burden to be endured rather than a source of insight.[46] Similarly, the Handbook endorses the practice of making public comments available to peer reviewers,[47] but it does nothing to encourage, never mind require, that peer reviewers consider even the most significant scientific content of public comments. Unsurprisingly, public comments are routinely ignored in practice, and public participation is typically constrained to presentations lasting a few minutes.[48]

This means peer reviews of draft EPA risk assessments tend to be dialogues between the peer review panel and Agency staff, who

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Forum on Regulatory Peer Review, Alexandria, Va., 2002. Available at http://www.rbbelzer.com/presentations.html#2002.

[45] Andrew Stark. Conflict of Interest in American Life. Cambridge, Mass.: Harvard Universitry Press, 2000.

[46] U.S. Environmental Protection Agency (2006, p. 49). "To ensure that public participation does not unduly delay activities, Offices should specify time limits for public participation throughout the peer review process."

[47] U.S. Environmental Protection Agency (2006, p 74 [distribution to peer reviewers is required for "influential scientific assessments"]). See also p. 49: "When employing a public comment process as part of the peer review, Offices should, whenever practical, provide peer reviewers with access to public comments that address significant scientific or technical issues."

[48] Robert F. Phalen. "Written Testimony Before the U.S. House of Representatives, Committee on Science, Space, and Technology, Subcommittee on Energy and the Environment, Hearing on 'Quality Science for Quality Air': *The CASAC - PM Committee - Setting Air Quality Standards*," 2011. "The public comments were not weighed and discussed by CASAC-PM in spite of the fact that most were well-reasoned and relevant. If the agenda included time for discussion of public comments and formal acceptance or rejection of their recommendations, the process might be improved."

might (or might not) have written (part of) the document. Unless they happen to be members of the peer review panel, primary researchers are rarely present and would in any case be relegated to cameo presentations during the limited time permitted for public comment.[49]

In the section below on remedies, I describe an alternative to this zoological style peer review in which public participation is taken seriously, and primary researchers have the lead in presenting scientific information but do not play a role in evaluating it.[50]

Federally chartered advisory committees

Even more than peer review panels, advisory committees are susceptible to politicizing science and scientizing policy. To the extent that they can locate a scientific rationale for the advice they want to provide, it can only make their recommendations more persuasive. Like Congress, the public often fondly hopes for scientific answers to difficult policy questions. If a policy choice can be made to appear scientific, it may have a much easier time gaining public acceptance.

One of the most striking examples of scientization occurred in 2008, after EPA finalized its revision to the ozone National Ambient Air Quality Standard. CASAC sent Administrator Stephen Johnson an unsolicited letter strenuously disagreeing with his decision. By itself, this might have been noteworthy but it should not have been overly controversial. After all, advisory committees that are independent of an agency's control must be free to offer whatever policy advice they see fit, and Agency officials are never obligated to accept policy recommendations from advisory committees.

But CASAC went much, much further. CASAC misrepresented its policy advice as science:

> *It is the Committee's consensus scientific opinion that your decision to set the primary ozone standard above this range [0.060 to 0.070 ppm] fails to satisfy the explicit stipulations*

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[49] See, e.g., William C. Adams. "Public Comment to CASAC Ozone Review Panel Teleconference." Available at http://www.epa.gov/sab/pdf/pub_comments_03-05-07_dr_wm_adams_uc-davis.pdf; accessed January 29, 2012.

[50] I use the term zoological to describe EPA peer reviews to reflect the fact that the public's role is strictly observational. Even tapping on the glass is prohibited.

> *of the Clean Air Act that you ensure an adequate margin of safety for all individuals, including sensitive populations.* [51]

This is wrong in multiple ways, and it should have drawn widespread opprobrium instead of acclaim. Science might be able to determine what human health effects occur at defined ozone concentrations, though even this ability becomes suspect as concentrations approach background. But it is impossible for science to determine what concentration is "requisite to protect the public health" or determine what constitutes "an adequate margin of safety." "Requisite" and "adequate" are squishy policy terms; they cannot be defined scientifically. But CASAC attempted to scientize air pollution policy—to make it appear as if science is the rightful venue for determining the meaning of "requisite" and "adequate." Equally disturbing, CASAC attempted to arrogate the authority to make these policy decisions despite knowing full well that Congress delegated them to the Administrator.

This incident exposed a serious defect in the Clean Air Act's procedures, one that has lessons for advisory committees generally. By asking CASAC to review the scientific record to ensure that it "accurately reflects the latest scientific knowledge," [52] but simultaneously ask CASAC to give policy advice to the Administrator concerning what the standard ought to be, Congress practically invited CASAC to scientize policy. For CASAC members, it was their scientific credentials and expertise that gave them power, which they willfully abused. And because they did so, it is entirely reasonable to be skeptical about the quality of CASAC's scientific review. Did CASAC also politicize the science to make it support members' personal opinions about air pollution policy? Has anyone conducted a rigorous review to find out?

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[51] Rogene Henderson. "April 7, 2008 Letter to Stephen L. Johnson from CASAC on 'Clean Air Scientific Advisory Committee Recommendations Concerning the Final Rule for the National Ambient Air Quality Standards for Ozone'," CASAC April 7, 2008 Letter on O_3 NAAQS. Washington, D.C.: U.S. Environmental Protection Agency Office of the Science Advisory Board, 2008, p. 2. Emphasis added.

[52] See, e.g., "Clean Air Act." 44 U.S.C. 7401 *et seq*. 1970. See § 7409(d)(2)(B), referring back to §108(a)(2).

SOME POSSIBLE REMEDIES

Several remedies can be envisioned that follow from my diagnosis.

Information quality

The key problem noted above is that EPA does not adhere to its information quality guidelines. It largely ignores its procedural and substantive commitments. It does not respond in a timely manner to requests for correction and appeals. When it does respond, it tends to obfuscate. When it acknowledges errors, it does not correct them.

These deficiencies are no doubt caught up in program offices' desire to defend their past or pending regulatory decisions. But that cannot explain the Agency's unwillingness to adhere to information quality principles and standards in its science program, which EPA leadership claims is not regulatory.[53]

A reasonable inference is that EPA's research programs may be infected by both scientization (the desire to make policy decisions through science) and politicization (the abuse of science for policy purposes). Requiring EPA research programs to fully adhere to information quality principles and standards would go a long way toward overcoming these problems if they exist. If they do not exist, then full adherence to information quality principles and standards would earn EPA the credibility it believes it is deserved, and once and for all refute its many critics.

There are simple reforms that Congress could make that would breathe life into the information quality paradigm, thereby achieving a

[53] This principle is highlighted in previous testimony to the Subcommittee without reference to applicable information quality guidelines. See Anastas (2011, p. 1). "IRIS assessments provide a scientific foundation for EPA decisions to protect public health across EPA's programs and regions under an array of environmental laws. While not regulations, IRIS assessments are critical to many Agency decisions… After becoming Administrator in early 2009, Administrator Jackson reviewed the IRIS program and asked the Office of Research and Development (ORD) in May 2009 to implement a new IRIS process that would revitalize the program and make it more responsive to the needs of the Agency. The aim of the new process was to ensure the highest level of scientific quality, integrity, transparency, and timeliness."

dramatic improvement in the quality of EPA science. In particular, Congress could require one or more of the following:

> Require full disclosure of all data, models and methods for any study used as the basis for a risk assessment or component thereof

There appears to be a broad consensus in favor of transparency and reproducibility, the two procedural information quality standards. Under applicable information quality guidelines, data, models, and methods must be fully disclosed such that qualified third parties can reproduce the agency's results and obtain essentially the same result. If third parties are unable to even make such an attempt, then the agency work product is per se insufficiently transparent and violates applicable standards. If third parties can make the attempt but cannot reproduce EPA's results, then the information should be presumed to fail the objectivity test. In either case, the information involved should not be disseminated, much less used for risk assessment.[54]

Agencies avoid the full force of this transparency standard by claiming, correctly, that published articles in scholarly journals do not disclose enough information to meet the transparency and reproducibility standards. Congress can best solve this problem by altering incentives.

Contracting regulations already permit Federal agencies to demand that recipients of Federal research funds submit their data upon request. Unfortunately, agencies still have the discretion not to ask, and they often do so precisely to avoid having to disclose the information to the public as the Shelby Amendment otherwise requires.[55] Congress could relieve Federal agencies of this conundrum

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[54] The scientific information classification scheme recommended to the Subcommittee by Dr. Moghissi also has significant merit as a way to identify where scientific knowledge is weakest so that investments in research could be targeted to have the greatest value. See A. Alan Moghissi. "Written Testimony Before the U.S. House of Representatives, Committee on Science, Space, and Technology, Subcommittee on Energy and Environment, Hearing on 'Fostering Quality Science at EPA: Perspectives on Common Sense Reform:' *The Need for Regulatory Science Transparency at the EPA*," 2011.

[55] Pub. L. 105-277, 112 Stat. 2681-495: "That the Director of OMB amends Section __.36 of OMB Circular A-110 to require Federal awarding agencies to ensure that all data produced under an award will be made available to the public through

by requiring them to obtain research data if they want to use a Federally funded study as the basis for risk assessment. Requiring disclosure imposes only trivial costs on the agencies and does not violate the contractual terms of any Federally-funded researcher. No burden would be imposed on anyone if the agency did not want to use a Federally-funded study as the basis for risk assessment, and no researcher would be compelled to accept Federal research funds to conduct a study likely to be useful in risk assessment.

If an agency wants to rely on a study that was funded by another party, whether that be a state, business, trade association, or nongovernmental organization, nothing currently prevents the agency from asking that this information be supplied, nor is there any general legal barrier to the other party providing it. States, businesses, trade associations, and nongovernmental organizations that want their research to be used for public policy should happily volunteer to provide it. Some do.

Moreover, an ever increasing number of scholarly journals now require disclosure as a condition for publication. Congress can expedite this trend by prohibiting Federal agencies from basing risk assessments on studies published by journals that do not practice full disclosure. Researchers who want their work to influence policy will seek publication in journals that require disclosure.

> Require that any study used as the basis for a risk assessment or component thereof adhere to substantive information quality standards

Information quality standards, particularly the standards of presentational and substantive objectivity, should not apply to all scientific research. Exploratory, hypothesis-generating research often has merit, but by its nature it often cannot comply. However, hypothesis-testing research should always comply, particularly if it is going to be used for risk assessment. By requiring crucial studies to adhere to substantive information quality standards, much of the controversy over study selection could be eliminated.

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the procedures established under the Freedom of Information Act." OMB's implementation of this provision was highly controversial among recipients of Federal research funds who considered the data they collected to be their private intellectual property.

Notice that I would not require prior publication in a peer-reviewed journal or give special weight to such studies. Journals publish studies for many reasons, some of which are incompatible with their use in risk assessment. Full disclosure is a much better threshold requirement. Deference should be given to studies that, after full disclosure, have been reproduced and not refuted.

Require that Agency risk assessments or components thereof adhere to substantive information quality standards

While it is crucial that key studies adhere to information quality standards, it is not sufficient. Considerable analysis is performed subsequent to the selection of key studies, so it is essential that information quality standards also apply to risk assessments and other derivative work products.

In practice, this would mean that cancer risk assessments (including those containing unit risk values) and noncancer risk assessments (including those containing Reference Doses or Reference Concentrations) would have to adhere to the information quality paradigm.

In the short run, this would be very difficult for EPA because, as I noted above, it is the published policy and practice of the Agency not to produce objective risk assessments. In the long run, however, this requirement would unleash a torrent of new research into more objective risk assessment methods. Currently, there is very little "market demand" for objective methods because EPA is essentially a monopsonist in this "market." That is, EPA is the only buyer; as long as EPA does not want objective risk assessment methods, the market will not supply any.

Enforcement

If Congress were to require EPA research programs to adhere to information quality principles and standards, it would have to devise a way to enforce this requirement. We know that hortatory appeals and executive certifications do not work. We also know that inviting judges to "do science" cannot be much of an improvement, for they are just as susceptible to the temptation to politicize science. Even if judicial

review never erred, it also would be an expensive remedy that only a few could utilize.

One way to reduce the cost of judicial review is to narrowly tailor it to take advantage of the courts' comparative advantage in administrative procedure. Thus, courts might be authorized to render opinions on agency adherence to published information quality principles and practices, but they must be kept away from substantive scientific disputes.

Peer review

Several specific reforms of EPA peer review could be considered.

Explicitly require peer reviews to address information quality

The reforms recommended above in the section on information quality would go a long way to solving this problem. They would make clear that adherence to information quality principles and standards is not optional for studies on which EPA intended to base a risk assessment, or for risk assessments themselves.

As I noted above, EPA's Peer Review Handbook gives short shrift to information quality. Congress could remedy this by explicitly requiring peer reviews to include rigorous information quality review. This should be done early in the process so that EPA does not commit itself to basing risk assessments on noncompliant studies. EPA could be sure early on that the studies on which it intends to rely are fully compliant and will not be the subject of a spurious later controversy. Information quality review also should be done later to ensure that subsequent analyses performed by the Agency also comply. Waiting until EPA has already published a draft risk assessment may be too late, for by that time Agency risk assessors often have dug in their heels.

Considerable effort would be needed to train scientist-peer reviewers in information quality principles and standards, or alternatively, establish information quality as a distinct discipline that must be represented on every peer review panel. I prefer training scientist-peer reviewers so that they become better equipped to detect information quality errors as a regular part of their own professional discipline. This has external benefits insofar as it would introduce

concern for information quality into journal peer review, and thus into scholarly research destined for journal publication.

Strictly limit scientific peer reviews to science

It might seem superfluous to make such a requirement explicit, but the record shows that it is needed. Peer reviewers have incentives to scientize policy, and EPA staff have incentives to ask peer reviewers to conduct their reviews in ways that at least implicitly ratify embedded policy decisions. By strictly limiting scientific peer reviews to science, it would be much easier to discern when any actor in the peer review process—EPA staff, peer reviewers, and public commenters alike—has exceeded the charge.

At a practical level, this would mean removing so-called "science policy" issues from peer review. This is highly desirable, for it is within the domain of "science policy" that politicization and scientization are most likely to occur. Also, removing "science policy" would make peer review a much easier task for scientists to perform. It would improve the scientific quality of the peer review charge, for controversies over embedded policy choices within the charge would go away.

If policy issues were removed from the scope of scientific peer review, the importance of balancing bias among members of a peer review panel would appreciably diminish. Instead of worrying about balancing different policy views, greater attention could be devoted to ensuring that peer review panels have diverse intellectual perspectives. When there is a coincidence of intellectual interests among peer reviewers or between the panel and the Agency, as the current regime encourages, the result can be an echo chamber.[56]

Make the selection of reviewers and the charge independent of the Agency

It's a well-known secret that the ability to select peer reviewers and write the charge creates the opportunity to control the outcome. For this reason, EPA should not control the charge and peer reviewers

[56] The echo is deafeningly loud when peer reviewers also share the same policy or "science policy" views as Agency staff—yet another good reason for strictly limiting scientific peer review to science.

should not be selected by EPA or its contractors.[57] In its Peer Review Handbook, EPA displays a high degree of skepticism about external parties conducting peer reviews of their own work products.[58] It is therefore hardly unreasonable for others to be similarly skeptical of peer reviews of EPA work products conducted by EPA.[59] A simple expedient might be to establish and maintain lists of qualified, independent panel members for each discipline and select the requisite number of members from each list by lottery.

In 2006, Regulatory Checkbook organized and conducted a scientific review that I believe follows another superior model that EPA could adopt. We followed OMB's draft peer review guidelines,[60] which were much stronger than the final version. We strictly limited the review to science—where possible, only primary scientific research was considered—and excluded all manner of policy considerations, such as the derivation of a unit risk factor. We focused on just four major scientific questions, thus conserving resources to address only the most important issues, with a separate peer review panel for each. Rather than control information exchange, we delegated that responsibility to universally respected, bona fide subject matter experts. So long as it did not stray into policy, we encouraged open discussion among all participants, including members of the public.[61] Finally, to avoid any interference by the sponsors, we established a Planning Committee whose role was to select the issues to be examined, select the subject matter experts and peer review panelists, write the charge, and coordinate the submission of the final reports for consideration by a scholarly journal subject to another round of peer review.[62]

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[57] It should be expected that contractors who want to maintain their business relationships with EPA are cognizant of EPA's desires with respect to panel selection.

[58] See U.S. Environmental Protection Agency (2006, p. 72).

[59] EPA appears to object even to peer reviews paid for by third parties where there is ample evidence of independence or no evidence of third party control.

[60] Office of Management and Budget. "Proposed Bulletin on Peer Review and Information Quality." Federal Register, 2003, 68, 54023-54029.

[61] We did not follow EPA's practice of limiting the participation of independent experts to staged five-minute didactic presentations.

[62] Richard B. Belzer, James S. Bus, Ercole L. Cavalier, Steven C. Lewis, D. Warner North and Richard C. Pleus. "The naphthalene state of the science symposium: Objectives, organization, structure, and charge." Regulatory Toxicology

Federally chartered advisory committees

A key lesson for Congress from the CASAC experience is to refrain from asking advisory committees to perform tasks that are inherently in conflict, such as conducting scientific review and giving policy advice.

Where this cannot be avoided, such as existing committees whose charters it is impracticable to change, advisory committees should be required to abide by relevant *Red Book* recommendations. They should "establish and maintain a clear conceptual distinction between assessment of risks and consideration of risk management alternatives," and ensure that their reports "clearly distinguish between the scientific basis and the policy basis" for their conclusions and recommendations. This can be easily enforced, such as by authorizing the EPA Administrator to ignore reports from advisory committees that demonstrably do not comply. The threat of being ignored is a powerful incentive.

What agency officials can do without Congressional action

I do not want to convey the impression that nothing can be done unless Congress acts. This is clearly not true. Obviously, EPA officials could, if they wanted to, insist that staff adhere to applicable information quality principles and standards. EPA officials could, if they

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and Pharmacology, 2008, 51(2(1)), 1-5, Kenneth T. Bogen, Janet M. Benson, Garold S. Yost, John B. Morris, Alan R. Dahl, Harvey J. Clewell III, Kannan Krishnan and Curtis J. Omiecinski. "Naphthalene metabolism in relation to target tissue anatomy, physiology, cytotoxicity and tumorigenic mechanism of action." Regulatory Toxicology and Pharmacology, 2008, 51(2(1)), 27-36, David Brusick. "Critical assessment of the genetic toxicity of naphthalene." Regulatory Toxicology and Pharmacology, 2008, 51(2(1)), 37-42, David Brusick, Mitchell S. Small, Ercole L. Cavalieri, Dhrubajyoti Chakravarti, Xinxin Ding, David G. Longfellow, Jun Nakamura, Eleanor C. Rogan and James A. Swenberg. "Possible genotoxic modes of action for naphthalene." Regulatory Toxicology and Pharmacology, 2008, 51(2(1)), 43-50, Fumie Y. Griego, Kenneth T. Bogen, Paul S. Price and Douglas L. Weed. "Exposure, epidemiology and human cancer incidence of naphthalene." Regulatory Toxicology and Pharmacology, 2008, 51(2(1)), 22-26, D. Warner North, Kamal M. Abdo, Janet M. Benson, Alan R. Dahl, John B. Morris, Roger Renni and Hanspeter Witschi. "A review of whole animal bioassays of the carcinogenic potential of naphthalene." Regulatory Toxicology and Pharmacology, 2008, 51(2(1)), 6-14, Paul S. Price and Michael A. Jayjock. "Available data on naphthalene exposures: Strengths and limitations." Regulatory Toxicology and Pharmacology, 2008, 51(2(1)), 15-21.

wanted to, direct the Science Policy Council to amend the Peer Review Handbook to explicitly include information quality review. They could, if they wanted to, insist that Agency peer reviews comply with the Peer Review Handbook.

EPA officials also could, if they wanted to, require Agency peer reviews to be strictly limited to science. It would take hardly any effort at all for EPA officials to modify the charters of Agency advisory committees and specifically include within each a requirement to abide by the *Red Book.*

In short, most of the reforms I have proposed actually require Congress to do anything. The reason why the Subcommittee is conducting oversight and considering legislation, however, is that EPA officials—officials appointed by Democratic and Republican presidents alike—have not made any of these reforms.

FINAL REMARKS

My diagnosis of the problems afflicting EPA science is not novel; indeed, I have specifically cited papers published in 1986 that make many of the same points.

To the best of my knowledge, Congress has never politicized EPA science by, for example, requiring it to estimate risk inaccurately or in a misleading way.[63] These are things EPA has done on its own, often by misusing the tools of risk assessment (the estimation of what risk is) to justify particular risk management decisions (the policy determination of what risk ought to be).[64]

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[63] In its 2004 report explaining and defending its risk assessment policies and practices, EPA staff say that Congress has, in fact, directed EPA to use risk assessment methods that are "protective" (i.e., tend to overstate risk). See National Research Council (1983, pp. 151, 153). However, the report does not provide a single example of a statutory provision requiring EPA to estimate risk in a biased manner. Every example given is either irrelevant to the question or it conflates risk assessment with risk management. See ibid., pp. 14-16.

[64] U.S. Environmental Protection Agency Office of the Science Advisor (2004, p. 14). "Congress establishes legal requirements that generally describe the level of protectiveness that EPA regulations must achieve and, infrequently, Congress imposes specific risk assessment requirements." "EPA seeks to adequately protect public and environmental health by ensuring *that risk is not likely to be underestimated*" (emphasis in original).

In this way, EPA risk assessors and other staff have scientized policy and politicized science. They have scientized policy by claiming that science can answer questions that science can inform, but not decide. They have politicized science by choosing not to estimate risk accurately. By scientizing policy, Agency risk assessors and other staff have taken away from Agency officials the authority and responsibility, delegated by Congress, to make policy decisions. They take away from policy officials alternatives that are well within the range of plausible interpretations of their statutory directives.[65]

The remedies I have proposed should not be controversial if the goal is to improve scientific quality while preserving the Agency's legitimate discretion under the various laws Congress has directed it to implement. They are grounded in the ideals of the National Academy's 1983 *Red Book*, yet recognize that the *Red Book* model has either failed or cannot be implemented. Instead of "establishing and maintaining a clear conceptual distinction between assessment of risks and the consideration of risk management alternatives," I believe it is time to effect a full and complete separation. I believe this is essential to restore science to its rightful place, freeing it from politicization, while at the same time aggressively policing the boundary between science and policy to ensure that policy making also is free from scientization.

Some recommend removing risk assessment from EPA, believing that it is simply not possible for science to be performed within "the political cauldron" of EPA because its "messy mix of politics, policy, economics, law, interests, and values" make it "not a good environment in which to develop and evaluate science."[66] I

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[65] EPA staff deny this, but unconvincingly. "[A]ny science policy position or choice used in the risk assessment process does not direct the risk assessment itself toward a specific risk management decision, e.g., the use of a specific risk estimate," they write. "Rather, the risk assessment informs the decision maker about the potential risks and uncertainties around the risk estimate(s). These characterized risks are then considered in light of the other factors before a decision is made…" (ibid., p. 13). Except that it misinforms decision makers, making it harder for them to take account of "other factors."

[66] U.S. Environmental Protection Agency Office of the Science Advisor (2004, p. 11). Professor Marchant advocates removing the production and review of science from EPA's jurisdiction: "it would be best if the science was developed and evaluated

understand the sentiment but I am not ready to give up, nor is it clear to me that giving up is a realistic option.

Thank you again for the opportunity to testify today on this important subject. I would be pleased to answer any question that members of the Subcommittee might have.

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separately, and in particular in a separate institutional context, from the more political decision-making process."

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