REGULATORY CHECKBOOK

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Committee on Science, Space, and Technology
Hearing entitled
"Quality Science at EPA:
Perspectives on Common Sense Reform- Day II"
February 3, 2012

Responses to Questions for the Record
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QUESTIONS FROM CHAIRMAN ANDY HARRIS

1. ***The Bipartisan Policy Center's 2009 report, "Improving the Use of Science in Regulatory Policy" was mentioned during the hearing. This report made several suggestions that may be useful in guiding this Subcommittee's efforts to reform regulatory science. Do you agree with any or all of these recommendations? Do you have any additional comments or advice in pursuing these goals?***

As a preface to my reply, I wish to make three observations that span the range of the BPC committee report's conclusions and recommendations. First, there should be no question that the committee approached its assignment with seriousness, public spiritedness, and the best of intentions. It is therefore inappropriate to judge its insights and commendations based on any factor other than merit.

Second, the BPC committee's task was enriched by the participation of individuals who had served, at one time or another, on both the analytic and decision making sides. This experience makes a fine illustration of Graham Allison's Model 3 of bureaucratic politics: "Where you stand depends on where you sit."[1]

Third, the good faith and rich experience of the members of the BPC committee do not automatically translate into practical or effective solutions.

[1] Allison (1971).

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Some of the committee's recommendations are basically fond wishes for someone—anyone—to implement by magic wand. Other recommendations appear to be plausible ideas that unfortunately are grounded on dubious premises.

The BPC committee's recommendations should be subjected to a sequential three-part analysis:

1. If the recommendation could be implemented immediately at no cost, would it solve the identified problem? If it wouldn't, then it is unclear why Congress should devote much time to it.
2. If the recommendation could solve the identified problem, is there a practical strategy proposed by which to implement it? If the recommendation cannot be implemented, then its interest will be limited to academics and theoreticians.
3. If there is a practical strategy by which the recommendation could be implemented, what unintended consequences could occur; which of them are likely; and how could they be prevented?

With that preface, my responses to each of the bulleted inquires follows below.

- ***"Studies used in the formulation of regulation should be subject to data access requirements equivalent to those under the Data Access Act."***

I am generally in agreement with the objective of the BPC committee recommendation, but it appears to be too timid. Data access rules "equivalent to those" under the Data Access Act cannot solve the problem the BPC committee identified. Agencies can and do behave strategically to evade the Shelby Amendment. They often rely substantially on the work of federally-funded researchers but intentionally do not obtain their data. Meanwhile, OMB Circular A-130 is burdensome and ineffective. In short, this recommendation fails the first element of my three-part test.

A SUPERIOR ALTERNATIVE

In my testimony before the Committee, I said the full disclosure of data, models, and assumptions should be required for scientific information that EPA (or any other agency) either disseminates in a manner connoting agreement or which it relies on, in whole or in part, for regulatory decision making. As I testified:

> Congress could relieve Federal agencies of this conundrum 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.[2]

In my testimony I also agreed with the BPC committee that no distinction should be made based on the source of research funding:

> 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.[3]

Even if it were true that industry-funded studies always pointed to lower risk and government/nonprofit studies always pointed to higher risk, that would not justify applying different disclosure standards. Rather, it reinforces the need for the same standards to apply to all scientific information, regardless of the source of funding or the direction in which the research might alter risk assessment.

- ***"The process of conducting literature reviews" and "the process of naming advisory committees" should be made more transparent.***

These excerpts comes from different recommendations addressing different issues, though with an overlapping remedy.[4]

LITERATURE REVIEW

The BPC committee correctly recognized that if the scientific record is not assembled well at the outset, the rest of the process will go badly, and transparency has been lacking with regard to this process. Further, the committee also noted that EPA's criteria for evaluating the literature lacked consistent principles, which is a discreet way of saying that Agency procedures are ad hoc, and in many cases post hoc.

[2] Belzer (2012), p. 23.

[3] Ibid.

[4] Bipartisan Policy Center (2009), p. 41 [Recommendation Three] and p. 18 [Recommendation Two].

What the committee did not say, but almost surely knew, is that EPA's opacity with respect to conducting literature reviews is intentional. Opacity maximizes the Agency's policy discretion to interpret scientific information as it sees fit. Thus, the committee's recommendation is very nearly a request that EPA bind itself to interpret and use science in predictable ways. Unless it is required by law, this is something neither EPA nor its advisory committees are likely to do. Thus, it fails the second element of my three-part test.

SELECTION OF MEMBERS OF ADVISORY COMMITTEES

The BPC committee's recommendation for transparency in the selection of scientific advisors is similarly at odds with the incentives of EPA officials, staff, and its scientific advisors. Each has incentives that are incompatible with each other, and with good government. Officials and staff alike tend to prefer scientific advisors who agree with them and be loyal defenders of their parochial interests. Officials and staff sometimes agree with each other, but sometimes do not. Thus, conflict is built into the process when an agency allows third parties inside.

It is useful to remember that advisory committees were the last generation's good-government solution to the problem of agencies failing to rely on the best available science. The BPC committee's conclusion that the advisory committee process needed reform indicates that this reform has not been successful and it has had significant unintended consequences. Among those unintended consequences is a new source of pressure to scientize policy.

Being a scientific advisor to EPA confers prestige and power, and for academics it also provides a potential trail to money in the form of research grants. Prestige is obvious; power arises because of the ability to influence policy; and research grants are the mother's milk of academia. It would be naïve to think that scientific advisors are motivated solely by altruism.

The BPC committee called for the process of naming advisory committee members being made more transparent, but it is not clear which problem the committee was trying to solve. The committee said there was a "proper" way advisory committees should be used; implied that agencies' actual use of them was not "proper"; and concluded that transparency in the selection of members would restore "propriety."[5] The committee did not explain how this would happen.

[5] Ibid. p. 68.

Transparency is certainly a good thing, but it isn't likely to be a solution to the underlying problem (i.e., failure to use the best available science) or advisory committees' unintended consequences (e.g., scientization). These unintended consequences can be reduced, but not eliminated, by strictly limiting the role of scientific advisory committee to science. For both scientific and policy advisory committees, there would be additional benefit in making committee selections randomly from lists of qualified individuals, thus reducing the potential for lobbying, logrolling, or various forms of corruption. Ironically, this would make the selection process less transparent, not more so.

RELATED ISSUES

I wish to comment upon one of the committee's recommendations in this area that I find troubling:

> **In general, papers in high impact, peer reviewed journals should be given great weight, and papers that have not been peer reviewed should be treated with skepticism.** However, the quality of peer review varies widely, and journal rankings and impact factors do not guarantee that peer review of a specific paper was performed adequately. **Agencies and scientific advisory committees need to extend their inquiry beyond simply ascertaining whether a paper was peer reviewed; peer review is a necessary but not sufficient determinant of quality.** That further inquiry might explore how the peer review was conducted, how the paper fits into the larger body of literature under review, and perhaps most important, the methodology behind the conclusions described in the paper (for example, how a cohort to study was chosen in an epidemiological study).[6]

This advice is internally inconsistent. The committee says that studies published in "high impact, peer reviewed journals" deserve "great weight," but then cautions that the "quality of peer review varies widely," which of course also is true for "high impact, peer reviewed journals." If that is so, then what could possibly be the justification for giving deference to these studies? It is a short step from giving deference to studies published in prestigious journals to giving deference to studies authored by prestigious researchers. Prestige is not a predictor of accuracy, and what we ought to be seeking to encourage is a scientific culture in which accuracy is what leads to prestige.

[6] Ibid. pp. 41-42; bold in original.

The additional criteria suggested by the committee are early steps of the pre-dissemination review required by OMB (and EPA) information quality guidelines. However, the BPC committee curiously excluded federal information quality standards from the scope of its work—an obvious lost opportunity.[7]

In my testimony, I recommended that Congress require that EPA risk assessments, components, and studies used as the basis for a risk assessment or component, adhere to information quality standards.[8] This is a much better path forward. It would establish a well-defined and consistent performance standard for all scientific information used in support of regulation. It focuses on the objectivity of scientific research and its utility for decision making, not weak, poorly correlated proxies such as the perceived prestige of the journal (or the researcher).

For this reason it is curious that OMB's peer review guidelines do not require adherence to federal information quality standards, even though information quality was advertised as their *raison d'être.* Information quality review also is missing from EPA's Peer Review Handbook.[9] Apparently EPA does not want its scientific peer reviews to get distracted by the burden of ensuring that information quality principles, including objectivity, are met.

- ***"Agencies should avoid turning repeatedly to the same scientists for service on advisory committees."***

This advice from the BPC committee is part of a series of elements in its second recommendation, the purpose of which is as unclear as the theme linking the elements is elusive.[10] Though the committee apparently found it easy to recommend against going to the same well too often, it did not make clear what might be wrong with its water.

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[7] Ibid. p. 43; footnote 6. This is peculiar. No less than nine references in the Report's bibliography concern federal information quality standards. Even more curiously, this footnote does not appear to be relevant to the text to which it is assigned.

[8] Belzer (2012), pp. 24-25.

[9] U.S. Environmental Protection Agency (2006), p. 17. Nothing in the Peer Review Handbook explains how to actually perform an information quality review.

[10] Bipartisan Policy Center (2009). The BPC committee's second recommendation is that the Administration promulgate guidelines implementing the committee's list of recommendations about when to consult advisory committees, how to appoint them, and how they should operate.

There are several problems that can arise if EPA relies repeatedly on the same scientists for advice. The agency may prefer to retain scientists who share the same perspective on the agency's mission and policy direction, or who are more easily managed by the career staff. These scientists would reflect too narrow a perspective, and easily could become so powerful that they are (or perceive themselves to be) de facto regulatory decision makers. As I noted in my testimony, in 2008 the Clean Air Scientific Advisory Committee (CASAC) seems to have succumbed to this misunderstanding of its role with respect to its review of the ozone NAAQS.[11] More recently, in its now-abandoned proposal to "reconsider" the 2008 ozone NAAQS, EPA Administrator Jackson appears to have welcomed the opportunity to implicitly delegate to CASAC the authority to set the standard.[12] The scientization of policy is inappropriate whether it is committed by scientists on an advisory committee or the Administrator herself.

At the same time, there may be good reasons for asking the same scientists to serve over an extended period. For example, a regulatory development process (e.g., the NAAQS) that takes five years may need multiple reviews. If the reviewers change midstream, there is a significant chance that the second group of reviewers will give advice that is contrary to that of the first. While the first group's advice might have been wrong, it's just as plausible that it was right and it is the second group's advice that isn't. The quality of EPA's science is not necessarily enhanced when it receives conflicting advice from multiple committees.

In my view, when EPA gets conflicting advice, it is likely that the reason is not because of the length of service of certain peer reviewers and advisory committee members. Rather, conflicting advice arises because the nature of their role is conflicted. This happens when scientist/reviewers are asked to conduct both a scientific review (which should be neutral and objective) and opine on policy (which cannot be). Whether there is churn among per reviewers and advisory group members may not matter a great deal if they limit their work to science. But it could matter a lot if they are providing policy advice, something the BPC committee explicitly advised against. Thus, the more important first step is to strictly limit scientific reviews to science and get advisory committees out of the business of doing both scientific review and giving policy advice.

[11] Belzer (2012), pp. 19-20.

[12] U.S. Environmental Protection Agency (2009), U.S. Environmental Protection Agency (2010a), p. 2943.

- ***Executive branch agencies need to "help clarify for both officials and the general public which aspects of disputes are truly about scientific results and which concern policy."***

The BPC committee's suggestions in this section of their Report are all interesting and potentially very useful, but they beg the question: why haven't any of them already been implemented? After all, like other regulatory agencies EPA has been subject to centralized review by OMB's Office of Information and Regulatory Affairs for consistency with various regulatory principles for over 30 years.

One answer is that abstract presidential directives and guidelines are not always consistent with the president's agenda or enjoy bipartisan congressional support. Even when these barriers do not exist, they are far from self-implementing. The OIRA professional staff is too small and its authority too limited to be as effective as its advocates hope and its detractors fear.

Even when the stars are properly aligned, OIRA's review process is not structured in a manner that enhances effectiveness. One obvious example: OIRA review occurs too late in the process to ensure that presidential guidelines have been met. Thus, even if guidelines that the BPC committee considered ideal could be drafted, neither OIRA nor anyone else could enforce them. What the BPC committee did not say, but which has to be true, is that the reforms it wants the President to implement are contrary to the bureaucratic interests of the agencies he superintends. Note also that the BPC committee did not propose that OIRA's authorities be expanded enough to enforce them, or that a new organization be established and given this authority.

There are many strategies that might be considered for ensuring that EPA (and other agencies) "clarify for both officials and the general public which aspects of disputes are truly about scientific results and which concern policy." In my testimony, I recommended that Congress require agencies to comply with Federal information quality guidelines and explicitly give the courts the limited authority to adjudicate adherence to these procedures and standards.[13] This recommendation is much more practical and easier to implement than yet another unenforceable presidential guidance document.

[13] Belzer (2012), pp. 21-25.

It satisfies at least the first two elements of the three-part test I presented at the outset.[14]

- ***"Policy makers should be wary of conclusions of risk that are expressed as a single number."***

The BPC committee's advice here is welcome but, if anything, seriously understated and naïve. The notion that risk can be reduced to a single number is a longstanding and durable myth, but unfortunately it is one that Congress encourages.[15] Risk assessment is scientifically uncertain and risk is inherently variable across any population, but policy makers across both the Executive and Legislative branches persist in seeking single number (and single word) characterizations of risk. The use of single numbers (and single words) to represent or describe risk is a common way that policy issues are scientized—i.e., where science is used to make it appear as if no genuine policy issue exists.

The proper way to report risk estimates is by first objectively characterizing the entire distribution, to the extent that is feasible, and then by conducting a rigorous analysis of the most important scientific uncertainties. Not only is distributional variability rarely reported and uncertainty analysis rarely performed, human health risk is not estimated objectively. If adherence to Federal information quality guidelines and standards were statutorily required in an enforceable manner, these longstanding problems would have a short shelf life.

- ***"Federal agencies need to experiment with ways to increase the number of scientists who participate in peer review."***

The BPC committee's concerns about the effectiveness of governmental peer review are certainly well-founded, but I am not persuaded by the committee's diagnosis, which depends on several dubious premises and factual claims that are not well supported by empirical

[14] The most likely unintended consequence would be judicial interference with science. My recommendation does not include giving the courts the authority to review and substantively opine on science, but the courts might not heed such a restriction.

[15] A non-EPA example of some interest: Congress directed the Department of Health and Human Services (through the National Toxicology Program) to determine whether substances are "known" or "reasonably anticipated to be" human carcinogens—special forms of the "single number" problem. However, neither of these conditions is discernable scientifically, and as a result the NTP's biennial Report on Carcinogens has little scientific merit. See Belzer (2012), pp. 19-20.

evidence. For example, it is not clear that peer review has ever been, as the BPC committee claims, "the primary guarantor of integrity in the scientific system."[16]

Scientific integrity has never been guaranteed by anything, and peer review would be a poor insurance policy. This is not because "[s]cientists may feel too burdened to review their colleagues' papers or may do so with insufficient care," or because "[p]eer review is no longer assumed to be a professional obligation," though both concerns may be valid. The reason is more mundane: the historic purpose of peer review has been to allocate limited research funds across competing proposals and to decide which manuscripts among competing submissions deserve to be published in scholarly journals whose pages are limited. Scholarly integrity is a product of training reinforced by character; it is not part of peer review. A more plausible reason for the decline in the quality of peer review, if indeed that has happened, is that academic institutions no longer spend as much time inculcating integrity among junior scholars and valuing character.

There is an increasing tendency for academic scholarship to be infused with policy advocacy. Whereas a generation ago, men and women chose scholarly pursuits to advance knowledge, it seems that an increasing proportion of them do so nowadays to advance hobby horse public policy objectives. This is a trend that so many academic institutions and professional societies foster that it is getting harder every day to find scientists to conduct peer review who are as interested in the science as they are in whether the science advances the achievement of their public policy preferences. For this reason alone, the BPC committee's suggestion that universities and professional societies do a better job fostering peer review seems unlikely to be effective. It fails at least the second element of my three-part test.

A larger problem is that governmental peer review is structured very differently from scholarly peer review and has a completely different objective. Whereas scholarly peer reviewers are never selected by the authors of the manuscripts they review, governmental peer reviewers often are. Whereas scholarly peer reviewers have substantial influence over whether manuscripts are published, governmental peer reviewers never do. Whereas scholarly peer reviewers are supposed to determine whether a

[16] Bipartisan Policy Center (2009), p. 45 (and pullout text on p. 46).

manuscript deserves to be published, governmental peer reviewers are asked to determine whether a risk assessment is correct.[17]

As a result of testimony given by several of the witnesses at the February 3 hearing, the Committee is now aware, perhaps for the first time, that peer reviewers in both scholarly and governmental settings virtually never review a study's underlying data. The Committee also appears to have become aware for the first time that peer review is a poor tool for ascertaining whether the conclusions of research are scientifically correct.

This misunderstanding preceded, but seems to have been exacerbated by, OMB's government-wide peer review guidelines.[18] The stated purpose of these guidelines was to provide a mechanism for pre-dissemination information quality review. Inexplicably, however, OMB's guidelines contained no requirement that peer review actually include pre-dissemination information quality review. Instead of providing a tool for preventing the dissemination of error, the guidelines made it possible for Federal agencies to use peer review to shield themselves from charges that information they disseminated is false.

For these reasons, and others, I am skeptical of the BPC committee's recommendations for improving peer review. Some of them are unlikely to help, even if they could be implemented at no cost, because they are too ambiguous (e.g., "strengthen peer review," "experiment with different ways of conducting peer reviews") or contrary to self-interest (e.g., "[u]niversities should do more to make service as a peer reviewer an expected and appreciated aspect of a scientist's career"). For other recommendations (e.g., "[s]cientific journals should improve the quality control of peer review," or have "clear, publicly accessible conflict-of-interest policies"), the BPC committee neglected to offer strategies for actually implementing them.

In my written testimony, I noted that much of the problem with governmental peer review is that the task relies on scientists but often involves substantial policy content. This policy content could be explicit (e.g., an agency seeks policy advice) or implicit (e.g., an agency seeks ratification of a risk assessment in which the agency's preferred policy is embedded in the methodology). I recommended that scientific peer reviews be strictly limited to science, noting several desirable attributes that would result.[19] In my experience organizing strictly scientific peer review, it has been a

[17] Belzer (2002).

[18] Office of Management and Budget (2005).

[19] Belzer (2012), pp. 21-25.

challenge to persuade scientists that policy matters are truly beyond the scope of the charge, but once they are convinced of this they find the peer review task much more interesting and intellectually stimulating.

One of the challenges of implementing strictly scientific peer review is it requires a fundamental cultural change. This is generally not in the interests of Federal agencies that sponsor a peer review program they consider effective, so it will not occur systematically without congressional action.

- ***"In presenting the conclusions of literature reviews, agencies and their scientific advisory committees need to be as open and precise as possible in discussing levels of risk and uncertainty."***

This is part and parcel of the tyranny of single number risk characterizations, discussed above. What the BPC committee did not acknowledge, but what everyone knows, is that it often is contrary to an agency's actual or perceived interest to acknowledge uncertainty, much less give full attention to it. Agency risk assessors may do the right thing and try to provide full disclosure and analysis of uncertainty, but agency officials often do not want this information. They may find the information too complex or just psychologically unsettling. Further, agency attorneys tend to dislike disclosure of uncertainty because they fear that doing so compromises the defense of promulgated regulations. Courts are obliged by *Chevron v. NRDC* (467 U.S. 837, 1984) to give substantial deference to agency expertise, and deference is easier to give if the agency's experts say they are sure about something even when they have hardly any idea at all.

Like a few other BPC committee recommendations, this one is mostly wishful thinking. Yes, it would be much better if agencies and their scientific advisory committees properly characterized variability and uncertainty when discussing risk. No, this is not going to happen unless and until Congress acts—to remove the ambiguity that creates agency discretion, to replace the Supreme Court's *Chevron* jurisprudence with something else, or to make the full disclosure or variability and uncertainty a nondiscretionary agency duty. To the extent that full disclosure is at least implicitly required by the Federal information quality standard of presentational objectivity, a simple remedy Congress can implement is to mandate that agencies adhere to this standard and make agency compliance judicially reviewable.

2. This Subcommittee's oversight has highlighted a pattern in EPA science: the Agency has protocols or guidelines to encourage transparency, objectivity, or information quality, but these standards are often ignored. What steps could be taken by Congress to ensure these standards are followed?

There are two general problems with the way agencies use guidance. First, they often publish it with the intent of achieving regulatory outcomes without bearing the burden of adhering to the rulemaking requirements of the Administrative Procedure Act. This practice is contrary to law but nonetheless widespread because of the savings to the agency if successful and the expense required to mount a legal challenge.[20] Second, when agencies use guidance properly, such as to limit their own exercise of discretion in order to reduce uncertainty, they often refuse to honor these commitments.

EPA's information quality guidelines provide an excellent example of the latter phenomenon.[21] These guidelines are generally well thought out, but EPA has not been forthright in honoring the commitments they contain. Similarly, EPA's Peer Review Handbook mentions information quality but includes no provisions for actually integrating it into the peer review process.[22]

Several years ago, OMB issued government-wide guidance on the use of guidance.[23] In addition to a number of housekeeping provisions, OMB established a pair of very simple and straightforward substantive principles:

- Guidance must "[n]ot include mandatory language such as 'shall,' 'must,' 'required' or 'requirement,' unless the agency is using these words to describe a statutory or regulatory requirement, or the language is addressed to agency staff and will not foreclose agency consideration of positions advanced by affected private parties" (§ II(2)(h)); and
- "Agency employees should not depart from significant guidance documents without appropriate justification and supervisory concurrence" (§ II(1)(b)).

[20] Congress could ameliorate this discrepancy by allowing plaintiffs who successfully challenge illegal guidance to recover their costs, perhaps including a penalty, from the agency's budget rather than the judgment fund.

[21] U.S. Environmental Protection Agency (2002).

[22] U.S. Environmental Protection Agency (2006).

[23] Office of Management and Budget (2007).

The first principle deals with the problem of using guidance illicitly for regulatory purposes. The second would require senior officials to explicitly waive limits on agency discretion contained in guidance and provide a justification for such waivers. In combination, these two principles reject the misuse of guidance for regulatory purposes and the failure to honor agency commitments.

To make sure that EPA (or any other agency) complies with these principles, Congress would have to codify them in statute.[24]

3. EPA's recently-released final Scientific Integrity Policy "[e]stablishes the expectation that when communicating scientific findings, Agency employees include a clear explication of underlying assumptions, accurate contextualization of uncertainties, and a description of the probabilities associated with both optimistic and pessimistic projections, if applicable." In your view, has the Agency adequately followed this policy in the past?

It is too soon for anyone to give an informed opinion concerning the extent to which EPA has followed this new policy, which has its genesis in a March 2009 Executive Order.[25] My concern with the policy is I have mixed feelings about whether adherence to it is always beneficial. I have no qualms with the excerpt cited above, or with numerous other excerpts and provisions, especially those which promote greater transparency and objectivity. However, these excerpts are accompanied by other text that is problematic at best.

A comprehensive scientific integrity policy must include provisions addressing both the politicization of science and the scientization of policy. After an extended delay, the Office of Science and Technology (OSTP) finally issued government-wide guidance in December 2010.[26] As my written testimony explained, this guidance handles the politicization of science ambiguously and the scientization of policy not at all.[27]

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[24] Agencies try to comply with this second principle without ever tying their hands by including a standard disclaimer, such as the one included in EPA's 2010 Scientific Integrity Policy. See U.S. Environmental Protection Agency (2010b).

[25] Obama (2009b).

[26] Holdren (2010).

[27] Belzer (2012), pp. 2-3.

In some respects, EPA's scientific integrity policy is somewhat better than the OSTP guidance. For example, whereas OSTP prohibits only public affairs staff from altering scientific information, EPA's policy "[p]rohibits all EPA employees, including scientists, managers, and other Agency leadership, from suppressing, altering, or otherwise impeding the timely release of scientific findings or conclusions."[28]

While EPA says its policy "builds upon existing Agency and government-wide policies and guidance documents,"[29] its record of compliance with these other policies and guidance documents does not set an encouraging example. This concern is intensified by the disconnect between EPA's establishment of a cadre of "Scientific Integrity Officials" with responsibility to "champion" scientific integrity, "provide oversight for the implementation" of the policy, and "act as liaisons for their respective Programs and Regions," but no apparent authority for them to actually do anything. Months of work on the guidance did not enable EPA to eliminate useless, circular language.[30] EPA says the policy repeats guidance issued by the Agency in 1999,[31] so it's not clear whether it contains anything new. In any case, EPA states that the policy is unenforceable by any entity other than EPA itself,[32] so this may not be a distinction with any difference.

In other respects, however, EPA's policy is much worse than the OSTP guidance. Like OSTP, EPA does not acknowledge the scientization of policy as a deficit in scientific integrity. Unlike OSTP, however, EPA's policy statement is not benign: it requires adherence to certain previously issued Agency guidelines whose very purpose is to scientize policy.[33] Why include this particular reference in scientific integrity guidelines? It ensures that the scientization of policy is exempt, while simultaneously making it appear that Agency officials "politicize science" if they ever try to reclaim the authority

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[28] U.S. Environmental Protection Agency (2010b), p. 4.

[29] Ibid. p. 1.

[30] See, e.g. Ibid. p. 3 ("To support a culture of scientific integrity within the Agency, this policy … [p]romotes a culture of scientific integrity").

[31] Ibid.

[32] Ibid. p. 2: The Scientific Integrity Policy "does not create any obligation, right or benefit for any member of the public, substantive or procedural, enforceable by law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees or agents, or any other person."

[33] Ibid. p. 4 (requiring adherence to EPA's Guidance for Risk Characterization).

delegated by Congress to make policy decisions that are now made "scientifically" by career staff.

Finally, EPA's scientific integrity policy includes an extensive section "[t]o assure the protection of Agency scientists," presumably from interference by Agency officials.[34] Notice that there is no parallel section protecting Agency officials from interference by Agency scientists in the exercise of their statutory authorities.

4. A recent joint report from the EPA's Science Advisory Board and Board of Scientific Counselors recommended that the Agency "include sustainability in its research vision" in order to allow "EPA to adopt sustainability as a core principle to inform decisions and actions." Is this emphasis on sustainability appropriate for EPA's research and science activities? Do you have any concerns about this new mission?

A comprehensive review of the SAB and BOSC foray into "sustainability" must await a clear definition of the term. EPA's existing definition is highly subjective and too ambiguous to be measured.[35] When a goal is subjectively defined or cant be measured, it can never be shown that it hasn't been achieved and it's anybody's guess whether achieving it is even a good thing.

The joint SAB/BOSC letter has similar difficulties. It recommends that EPA's Office of Research and Development

> include sustainability explicitly in its research vision, invoke a definition of sustainability shared across ORD, and demonstrate clearly how planned research relates to the key components of sustainability (the environment, the economy, and society).[36]

In lieu of a coherent definition, SAB/BOSC point to a recent National Research Council report, which also lacks a clear definition.[37] The NRC committee's review, which EPA sponsored, begins with numerous additional caveats. For example, the committee did not examine whether

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[34] Ibid. p. 5; Sec. IV(A)(3).

[35] U.S. Environmental Protection Agency (n.d.).

[36] U.S. EPA Science Advisory Board (2011), p. 6.

[37] National Research Council (2011), p. 3. "'Sustainability' and 'sustainable' mean to create and maintain conditions, under which humans and nature can exist in productive harmony, that permit fulfilling the social, economic, and other requirements of present and future generations."

"sustainability," so defined, is consistent with the statutes that govern EPA's authorized activities.[38]

It is always a concern when a Federal agency embarks on a new mission that is not explicitly authorized by law, and even more so when cheered on by scientists whose advice is sought primarily because they happen to embrace that mission. Public choice theory predicts that agencies will do this to expand their authority, power, staff, and resources. This is particularly characteristic of agencies such as EPA that have largely achieved the statutory objectives Congress originally assigned to it. Like private firms, agencies strive to reinvent themselves, including the creation of new missions, when it becomes clear that the need for their goods or services has dwindled, or they have become irrelevant or overcome by technological change. Federal agencies differ, however, insofar as they have no constitutional role to engage in activities that Congress has not authorized.

This suggests an inherent weakness in both the SAB/BOSC and NRC reports, and of course EPA's approach as well. Both reports could have, but did not, examine the extent to which the complicated and sometimes inconsistent patchwork of statutes that EPA implements has the perverse effect of making it harder for "humans and nature [to] exist in productive harmony." An obvious example might be the regulation of criteria air pollutants; the Clean Air Act can be interpreted to require the $PM_{2.5}$ and ozone NAAQS to be set at zero, in which case the statute is a suicide compact for humans and nature alike.

5. There was some discussion about the importance of objectivity and the role of peer review in EPA risk assessments.

a. Please describe how greater objectivity in assessments can be achieved, and what the practical effects of these improvements would be.

Among the witnesses testifying before the Committee on February 3, there appeared to be universal agreement that objectivity is not optional in science. Objectivity is an essential attribute of the scientific method, one that

[38] Ibid. pp. 17-18. The NRC committee attempts to show that Congress authorized EPA to implement sustainability via the National Environmental Policy Act of 1969. This logic is circular. NEPA did not establish "sustainability" as a governing principle; rather, President Obama borrowed hortatory language from NEPA to define "sustainability," whose definition the NRC committee then used. See Obama (2009a), p. 52126. Sec. 19(l).

is required via government-wide and EPA information quality guidelines.[39] Sometimes, objectivity (or one of its synonyms, "accuracy") is explicitly required by law.[40]

The hearing did not effectively distinguish between "science" and "risk assessment," however. EPA risk assessments are routinely described as scientific, even by Agency officials.[41] This is not correct. EPA risk assessments are notoriously lacking in objectivity, and as I testified before the Committee, this is a matter of design, not accident.[42]

Objectivity in risk assessment would serve three crucial purposes that current practices do not. First, it would ensure that EPA officials, Congress, and the public had unbiased information about the risks within EPA's jurisdiction. Second, it would enable these risks to be ranked so that resources devoted to risk reduction could be rationally allocated. Third, the authority to make risk management decisions that Congress has delegated to Agency officials would finally be made by those Agency officials, not by Agency scientists and career program managers with strong policy views.

b. Please describe the different types of peer reviews that science funded by or used by EPA may be subjected to, including which areas raise the most concerns.

As I have noted elsewhere in these replies and in my written testimony, peer review takes several different forms. Moreover, the purpose of scholarly peer review (to ration scarce journal pages) is fundamentally different than the purpose of governmental peer review (to ascertain what is correct). The procedures used for the former are ill-suited for the latter. For this reason, too much emphasis has been placed on scholarly peer review.

EPA peer review is governed by OMB guidelines and EPA's Peer Review Handbook, which have useful features but serious limitations and defects, as I have already discussed. To recap, these include too much Agency influence

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[39] Office of Management and Budget (2002), U.S. Environmental Protection Agency (2002).

[40] See, e.g., Clean Air Act, Sec. 108(a)(2): "Air quality criteria for an air pollutant shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities" (emphasis added).

[41] See, e.g., Anastas (2011), oral testimony.

[42] Belzer (2012), p. 5.

over the selection of reviewers and absolute control over their charge. EPA's peer review process is designed to maximize concordance with EPA's policy objectives. Finally, peer reviews of EPA risk assessments are suffused with risk management policy judgments.

In my testimony, I recommended that EPA peer reviews be strictly limited to science. I also suggested other reforms to the process, such as giving the most knowledgeable researchers on a scientific issue the responsibility of educating peer reviewers and coordinating open debate in which the public could actively participate. Unlike EPA practice, peer reviewers would never be drawn from the ranks of researchers who have published research or taken positions on the specific issue.

QUESTIONS FROM REP. RANDY NEUGEBAUER

1. What type of research does the EPA currently conduct to confirm predicted health outcomes of previously promulgated rules? In what ways can we improve existing efforts to examine the real effects of EPA rules, and what else can the Agency be doing to increase accountability for health and environmental predictions?

I am not aware of any significant EPA effort to confirm predicted health outcomes for previously promulgated rules. The closest thing I can think of is EPA's reconstructions of the benefits and costs of the Clean Air Act, as it was required to do under Section 812.[43] These reports do not confirm anything, except perhaps the foolishness of asking an agency to conduct its own performance evaluation.[44]

If Congress is serious about estimating how actual health outcomes compare with predictions, it must ensure that the review is conducted rigorously, independently, and transparently. Not only does this exclude EPA from performing the review, it also excludes the National Academy of

[43] See most recently, U.S. Environmental Protection Agency (2011).

[44] For a review of EPA's first foray into self-examination in this area, see Lutter and Belzer (2000).

Sciences, which does not practice transparency in the selection of experts,[45] committee deliberation,[46] or internal peer review.[47]

2. Are there any legitimate concerns about making public the data sets that attempt to justify EPA regulations? Are there real concerns about confidentiality, and if so, do they outweigh the necessity of accountability, transparency, and open and sound scientific examination?

There are only two areas in which confidentiality is a legitimate concern in human health risk assessment. The first involves confidential business information, such as perhaps studies performed on proprietary mixtures. I am unaware of any serious controversies in this area, but they may exist.

The second involves personally identifiable information, which epidemiologists long ago learned how to anonymize. It is an exceedingly rare study in which the identity of subjects must be known by the researchers and statisticians analyzing the data. Usually, knowledge of subjects' identities, whether they belong to a case or control group, and similar matters are purposely hidden from researchers themselves to ensure objectivity.

Researchers often desire not to disclose their data because they consider it their own intellectual property. The case for this is very weak when the data collection was publicly funded, but strong otherwise. In my testimony, I offered a straightforward solution: EPA should be required to fully disclose any data it intends to rely upon for risk assessment or any component thereof. Disclosure of federally-funded research, to which the government already has a right, would be mandatory if the study met this condition. Similarly, any third party that wants EPA to rely upon its data would have to meet the same disclosure standard.

My approach would impose no involuntary burden on researchers, federal or otherwise. Researchers could decide whether to restrict access to their data or influence public policy, but they no longer would be allowed to

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[45] The National Academies (2003), The National Academies (2005), p. 6.

[46] The National Academies (2005), p. 10. "Committee meetings, particularly as the committee gathers information, are usually open to interested individuals and the news media. However, meetings are closed when the committee is deliberating to develop its findings and during discussion of financial and personnel matters. Closed meetings are not open to the public or to any person who is not a committee member or an official, agent, or employee of the Academies."

[47] The National Academies (2008).

do both. Full disclosure must be the price for seeking to influence public policy, regardless of the source of funding.

QUESTIONS FROM REP. PAUL TONKO

1. Private Consulting.

Prior to the February 3rd EPA E&E Subcommittee hearing, Ranking Member Mr. Miller asked you to provide a list of the clients for whom you conduct private consulting work that may have an interest in the subject matter of that hearing. You declined to identify any of your past or present clients because you claimed a "confidentiality agreement" exists between you and your clients and that providing this basic information would violate that agreement. It is my understanding that the majority of "confidentiality agreements" revolve around the specific issues that a 'client' hires a 'contractor' to perform, particularly the results of that work. It is less common that a "confidentiality agreement" would bar from public disclosure the mere fact that a business relationship exists between a client and a contractor.

- ***Please list all clients you have signed a confidentiality agreement with broadly related to the subject of environmental science and/or regulatory issues over the past five years.***

The public disclosure of the existence of a confidential relationship would be tantamount to breaching its contents. As I said in my reply to Ranking Member Miller, I intend to honor these agreements and thus respectfully decline to identify past and present clients.

It is clear from information already in the public domain that you worked for the U.S. Department of Defense, through a consulting agreement with Booz Allen Hamilton; advising DOD on issues revolving around the chemical Perchlorate in 2003 and 2004.

- *Please indicate if you still have a business relationship with Booz Allen Hamilton and/or DOD? If not, please indicate when that relationship ended?*

I do not have a current business relationship with Booz Allen Hamilton and/or DoD. I believe that my previous relationship ended in April 2005.

2. Public Disclosure.

At the Feb. 3rd hearing you said: "When I do things that are public, when I put my name on something, a piece of work that I've produced then I disclose who I did it for." It was unclear from your response, however, what work products you consider to be "public".

- ***Please provide a list of work products you have produced over the past five years where you publicly disclosed who you did this work for, as you indicated you had done in your congressional testimony. Please include the title or name of the work product, the client's name you performed the work for, and where and when this work was presented or appeared.***

I have uploaded to my personal website at www.rbbelzer.com every publication, presentation, public comment, or similar work product that I have been able to locate—peer-reviewed or otherwise. For work products that are covered by a copyright owned by someone else, I provide links to web sites where copies can be purchased. I also have disclosed documents I authored on behalf of the Federal government.

Some of this work pre-dates the Internet era, however, so my website is regrettably incomplete.

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