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Administrative Conference of the United States Forum

The Administrative Conference of the United States is an independent federal agency dedicated to improving the administrative process through consensus-driven applied research, providing nonpartisan expert advice and recommendations for improvement of federal agency procedures. Its membership is composed of innovative federal officials and experts with diverse views and backgrounds from both the private sector and academia.

Science in the Administrative Process [message #31] Thu, 13 October 2011 11:07

Reeve Bull (Staff)

Messages: 6

Registered: September 2011

Welcome to the forum for the Science in the Administrative Process project. On this forum, members of the Administrative Conference's Committee on Regulation will discuss research that Professor Wendy Wagner (University of Texas Law School) has conducted for the Science in the Administrative Process project. Members of the public are also invited to submit comments on Professor Wagner's research generally and on other comments submitted to the forum.

The forum is now available for the posting of comments. It will remain available until December 15 at the latest. If the discussion is to conclude prior to December 15, the Conference will announce the closing date at least one week in advance on this forum and on the Science in the Administrative Process project page on the Conference's website (www.acus.gov).

Please find attached to this posting an outline describing Professor Wendy Wagner's research plan for the Science in the Administrative Process project. Committee members and members of the public can discuss this proposed research, as well as any other issue relating to the Science in the Administrative Process project, in the comments.

Should you have any questions about the use of this forum, please do not hesitate to contact Administrative Conference Attorney Advisor Reeve T. Bull at (202) 480-2083 or rbull@acus.gov. We look forward to hearing your thoughts in this discussion thread.

- Attachment: COR Science Project Wagner outline 10-31-11.pdf
  (Size: 409.57KB, Downloaded 65003 times)

[Updated on: Wed, 02 November 2011 09:13]

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Re: Science in the Administrative Process [message #32 is a reply to message #31]

Wed, 02 November 2011 09:34

Jonathan Siegel (Staff)

Messages: 2

Registered: September 2011

Welcome, everyone, to the ACUS forum. I am looking forward to participating in this discussion among committee members, staff, our consultant, and the public. I hope that this new and innovative method of conducting a committee meeting will lead to a productive discussion of Professor Wagner's project outline and that it will improve the project.

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Re: Science in the Administrative Process [message #33 is a reply to message #31]

Mon, 07 November 2011 10:48

Jonathan Siegel (Staff)

Messages: 2

Registered: September 2011

To get our discussion started, perhaps it would be useful to recall our prior, face-to-face committee meeting at which the committee discussed Professor Wagner's original outline for the project. The committee's view was that the outline was too broad and covered too many topics. The committee recommended that Professor Wagner narrow the focus of the project.

In response, Professor Wagner's revised outline focuses on "strengthening internal agency processes for communicating how it uses science for regulation." Wendy, could you comment on the reasons that led you to choose this focus for the project?

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Re: Science in the Administrative Process [message #34 is a reply to message #33]

Mon, 07 November 2011 13:01

Wendy Wagner (ACUS)

Messages: 6

Registered: October 2011

Thanks for kicking this discussion off, Jon.

The focus of the study -- stated in a few words -- is to assess the transparency of the agencies' use of science, primarily in informal rulemakings. The lack of transparency is a problem raised in the recent NAS Formaldehyde Report and referenced in both President Obama's initial letter and in OSTP's subsequent

memorandum on improving the agencies' use of science. This particular problem was also referenced by several committee members and public commenters during our meeting last May.

The topic seems to be a good starting point for a more sustained, graduated exploration of science in the regulatory state. Understanding how an agency is using science in a rulemaking is a critical first step to ensuring productive oversight by stakeholders, the courts, and political processes. Assessing how an agency explicates its use of science also illuminates whether the agency is making the best use of the available information, including internal studies by agency scientists. This topic will even provide preliminary information about how and when an agency elects to use science advisory boards, external peer review, or other intermediate mechanisms of scientific review as part of its rulemaking process. For a fuller discussion of these and other justifications, see pages 2-4 of the outline.

The study will focus on four agencies in particular -- EPA, FDA, NRC, and DOI. The research will consist of interviews with agency staff, the collection of any and all records on the topic, and the integration of several case studies.

I look forward to your comments on this project.

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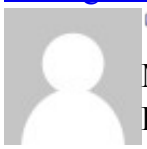
Re: Science in the Administrative Process [message #35 is a reply to message #34] Thu, 10 November 2011 09:36



gillian metzger
Messages: 1
Registered: November 2011

Wendy --

Thanks for the additional explanation and the write-up. I missed the initial meeting on the project but it sounds like you have tried to narrowed the project to focus on one important internal dimension of agency use of science.

I had two follow up questions. First, you mention in passing some possible payoffs for interagency coordination by more expeditious identification of points of disagreement(#4, p. 4 of the draft outline). And interagency coordination is the subject of some of your proposed questions. But I'd welcome further explanation of how you see transparency contributing to better inter-agency coordination, and particularly how this might lead to more expeditious identification of disagreements as you suggest. Part of my confusion here is that in proposed reforms you stress having agencies write up and include the statement of their use of science in the preamble of a proposed rule, which seems late for purposes of encouraging interagency coordination.

Second, do you expect to explore the relationship between transparency practices and other internal features of the agency's use of science, such as the role science advisors play, the form of internal rulemaking process, the role scientific staff play in that process, and--related to my first point--use of scientific expertise in other agencies? My intuition would be that how the rulemaking process is structured may well play a role in transparency and changes in such structures might prove quite useful in producing greater transparency. It also

seems like this could be a way to start generating some information about the effect of such internal structures on agencies' use of science generally. But I didn't see questions that seems geared to identifying how such internal structures were used by the agency, and wasn't sure whether you saw this more as a topic for future work investigatning the impact of such structures generally.

Gillian

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Re: Science in the Administrative Process [message #36 is a reply to message #34]

Mon, 14 November 2011 16:09

Peter Strauss (ACUS)
Messages: 3
Registered: October 2011
Location: Columbia Law School

Wendy --

Let me add a couple of thoughts to Gillian's.

1) As you remark, "science" covers a multitude of possibilities. In his short book, "The Honest Broker," Roger Pielke, Jr. valuably distinguishes between the kinds of issues that can be appropriately resolved by reliable inquiry into observable facts (is a tornado approaching?), "tornado science," and others that cannot, "abortion science." Then there are soft sciences and hard sciences, physics and psychology. It would be helpful to be clear which you are addressing and perhaps, as well, to be clearer than in my impression the proposal now is about the difference between what is conventionally described as risk/science assessment and risk/science management. My impression is that you are addressing only the former, and that part of the challenge lies in getting staff to be transparent about the limits on what risk/science assessment can identify. The uncertainty range that NRC staff called the area for "engineering judgment" is part of what needs to be -- and may be most difficult to get -- acknowledged.

2) All four of your target agencies are, appropriately in my judgment, largely in the hard science business, although some things they might consider (e.g., EPA or NRC on public risk perception as an arguable basis for priority choices) are decidedly on the "soft" side. For starters, at least, you might be clear that your focus is on staff approaches to "tornado science" and its uncertainties plus, perhaps, the accurate identification for decisionmakers of areas that "science," as such, is unlikely to resolve (though it might help to clarify).

3) The Advisory Committee on Reactor Safeguards at NRC (http://www.nrc.gov/about-nrc/regulatory/advisory/acrs.html) and the Clean Air Science Advisory Council in EPA (http://yosemite.epa.gov/sab/sabpeople.nsf/WebCommittees/CASA C) (also NIOSH in relation to OSHA) are congressionally chosen approaches at least ostensibly created to produce honest, expert, and transparent hard science advice. In my judgment such institutions ought to be a part of your inquiry, and some of their members among those you interview.

4) Were you to submit your interview protocol in writing, in my judgment (recalling how such things were

handled at NRC in what were probably easier times) you'd get nothing of real value back. Look at documents if you can, but I hope you will be doing interviews viva voce -- with whatever assurances of confidentiality you can provide. And in those interviews I would try to probe the question, how much hands-on your interviewees perceive there is by "management" of their scientific inquiries/judgments. At NRC the squelching of staff views by intermediate staff managers led directly to the first Indian Point hullaballoo. Your questions don't directly ask about that; shouldn't they?

You might think to provide the Formaldehyde report in advance of interviews, saying it suggests at least some of the questions you hope to talk about.

I'm attaching a book chapter I wrote a couple of years ago on "Possible Controls over the Bending of Regulatory Science," whose profound debt to your prior work with Tom McGarity you will quickly appreciate, in the hope it might prove useful to you. (The book is Gordon Anthony et al., Eds, Values in Global Administrative Law (Hart 2011).

Peter

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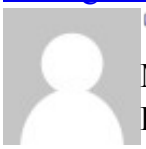
Re: Science in the Administrative Process [message #37 is a reply to message #36]

Tue, 15 November 2011 13:16



Wendy Wagner (ACUS)
Messages: 6
Registered: October 2011

Gillian and Peter,

Thanks for your terrific comments and questions.

1. As you both intuit, various internal agency processes are emerging in the course of the study that appear to facilitate heightened transparency of the role that scientific information is playing in the decision-making process. For example, I've learned that the NAAQS process includes a number of innovative features for integrating science into the regulatory process that go well beyond the use of science advisory boards like CASAC. Indeed, the identification of these unique, science-based processes is likely to form the basis for at least one set of recommendations. This process-focus of the study then ties into Gillian's first question. More elaborate internal agency processes for scientific fact-finding, when done properly, seem capable of facilitating better interagency coordination much earlier in the process, well before the NPRM.

2. Peter's comment urging me to be more explicit in identifying the type of science under study is also quite helpful. I now imagine a short introductory section that directly responds to his questions. In terms of my answers, though, while the study does focus primarily on natural (rather than social) sciences, the science-based regulatory projects under study (e.g., endangered species decisions, nuclear reactor safety, pesticide licensing, and food regulation) include both risk assessment and risk management decisions that are often comingled. Regardless of what I find, however, ultimately trying to discuss the features of the science-policy under study in an introductory section may be a valuable contribution in its own right.

3. The interview protocol has served only as an abstract checklist and I agree that it is incomplete and won't get at many underlying problems in the agencies. In truth, I have tried to engage each interviewee on his/her own turf and press for information both on successes and problems, although I haven't had much luck in learning about the problems. (In early interviews I mistakenly promised confidentiality which I understand is not possible/recommended for ACUS studies; yet even in those confidential interviews, I did not get very far on the problem development side). Of course interest groups are happy to fill in the gaps in identifying problems with agency's science-based rulemakings, but their perspective is not comprehensive. In short, any tips you have for extracting negative information out of agency employees would be great. Sharing the NAS formaldehyde report in advance of the interview (at least the last chapter) is a terrific idea, by the way, and I will definitely do that in the future.

Thank you again for taking the time to offer such thoughtful comments. And thank you Peter for attaching your article, although I am afraid I will need another ACUS tutorial to figure out how to access it. If you have further ideas or reactions, please send them along.

All the best, Wendy

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Re: Science in the Administrative Process [message #38 is a reply to message #36]

Tue, 15 November 2011 13:48

Reeve Bull (Staff)
Messages: 6
Registered: September 2011
Please see the attached book chapter by Professor Strauss.

- Attachment: Ch6 Strauss.PDF
  (Size: 296.37KB, Downloaded 62840 times)

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Re: Science in the Administrative Process [message #39 is a reply to message #37]

Tue, 15 November 2011 14:01

Peter Strauss (ACUS)
Messages: 3
Registered: October 2011
Location: Columbia Law School
One way to get negative indicators might be to interview past and present ACRS and CASAC members about their perceived successes and failures in transmitting science to NRC and EPA staff and, ultimately, the Commission and the Administrator. For an old story of the problem, look for the Senate hearings in January or February of 1976 into Robert Pollard's accusations of safety issues at Indian Point, that had been sat upon

at the staff level. An early Commission press release is here, pbadupws.nrc.gov/docs/ML1115/ML111590343.pdf, and I have tried to attach it; barriers to staff-Commission communication were an important element of post-Three-Mile_island analysis. See the Report of the Commission on the Accident at Three Mile Island and Shulman, 56 Notre Dame L.Rev. 351 (1981).

- Attachment: Pollard press release.pdf
  (Size: 101.21KB, Downloaded 62662 times)

Peter

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Re: Science in the Administrative Process [message #40 is a reply to message #39] Tue, 15 November 2011 14:10

Wendy Wagner (ACUS)
Messages: 6
Registered: October 2011

Terrific. Thanks! NRC now has a dissenting scientist policy (called the differing professionals program) that I suspect was developed in response to this type of staff suppression. It is tough to know whether other managerial/bureaucratic pressures nevertheless squelch dissenting scientists, even with this policy in place. Do you have any insights on that?

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Re: Science in the Administrative Process [message #41 is a reply to message #40] Tue, 15 November 2011 14:16

Peter Strauss (ACUS)
Messages: 3
Registered: October 2011
Location: Columbia Law School

I didn't know about this policy and share your suspicions. Do/should other agencies have similar, essentially whistleblower regulations? As to its success, I have no information; and, that could be a question to pursue in talking with NRC people. How often has it been invoked? Have situations in which it could have been, but was not, invoked come to light? With what follow-up?

Peter

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Re: Science in the Administrative Process [message #42 is a reply to Tue, 22 November 2011 15:07

message #41]

Susan Dudley (ACUS)
Messages: 2
Registered: November 2011

Thank you Wendy. Recommendations for making more transparent how agencies use science to inform regulation would be worthwhile.

I'll echo Peter's request for more clarity regarding what you're defining as science. Your response recognizes that, for the areas you've selected, risk assessment and risk management are often "comingled," which I think needs more examination in your study. Greater transparency in the science underpinning regulatory decisions demands a clear distinction between science and policy judgments. As the Bipartisan Policy Center's 2009 report stated: "A critical goal of any new procedures for establishing regulatory policy must be to clarify which aspects of a regulatory issue are matters of science and which are matters of policy (e.g., economics or ethics)." (BPC, 11) http://www.bipartisanpolicy.org/library/report/science-polic y-project-final-report

Susan

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Re: Science in the Administrative Process [message #43 is a reply to message #42] Tue, 22 November 2011 16:24

Wendy Wagner (ACUS)
Messages: 6
Registered: October 2011

Thanks for your comment, Susan. I'll do my best to draw distinctions between science and other forms of knowledge and judgment in this new, introductory section I reference above. Of course one must keep in mind that many (indeed most) folks working in science-policy studies believe that one cannot separate science from policy in a coherent way, so whatever I do produce will please some and annoy others. Still, I agree it will be very helpful to set out that background and will be sure to include it in the report.

If you have any sources you think I should read on this score, please feel free to pass them along. Thanks again!

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Re: Science in the Administrative Process [message #44 is a reply to message #34] Wed, 23 November 2011 13:09

Richard B. Belzer
Messages: 4
Registered: November 2011
Location: Mount Vernon, VA

I'm going to play catch-up here, reading and responding to several of the comments posted so far.

"The focus of the study -- stated in a few words -- is to assess the transparency of the agencies' use of science, primarily in informal rulemakings. The lack of transparency is a problem raised in the recent NAS Formaldehyde Report and referenced in both President Obama's initial letter and in OSTP's subsequent memorandum on improving the agencies' use of science."

This is certainly a challenging task. Reading your outline, however, I am confused about the research method. Focusing on 4 agencies many be sensible given budget constraints, but it is important to recognize up front that you will not be able to draw any generalizations based on such a sample.

Moreover, you say you are "seeking relevant documents from within the agencies," conducting "interviews with agency staff (past and present) and knowledgeable stakeholders," and relying "where appropriate, on other government-related studies by NAS, OTA, GAO, and the general literature." Each of these approaches has significant limitations.

To be concrete, you can seek "relevant documents" all you want, but there is hardly any reason to be confident that such documents exist; that if they exist you will obtain them, given their almost certain protection from disclosure; or that any documents you do obtain will be representative and not self-serving. How will you deal with these problems? How will you test the validity of whatever document you are given?

Similarly, interviews are notoriously unreliable. You can't interview everyone, and there is no reason to believe that your sample will be representative, even for just the 4 agencies you are examining. Nor is there good reason to assume that interviewees won't behave strategically, especially because OMB's role is a central issue but OMB personnel (past or present) are not on your interview list. How do you plan to validate the responses you obtain?

Finally, relying on existing literature doesn't get you very far. Each of the organizations you cite--NAS, OTA (RIP), and GAO all have their own perspectives and biases, often resulting from disparate charges that were the foundation of their work, and limited access to the internal documents that you are seeking. At best, the existing literature can generate hypotheses for testing, and of course, many of these hypotheses will be impractical or impossible to test.

You also say:

"Understanding how an agency is using science in a rulemaking is a critical first step to ensuring productive oversight by stakeholders, the courts, and political processes. Assessing how an agency explicates its use of science also illuminates whether the agency is making the best use of the available information, including internal studies by agency scientists. This topic will even provide preliminary information about how and when an agency elects to use science advisory boards, external peer review, or other intermediate mechanisms of scientific review as part of its rulemaking process."

I don't see how your research method can answer any of these questions.

What seems to be missing from your outline, yet is crucial for establishing a clear research strategy, is a clear

definition of the problem. To give one obvious example, in Section A.1 you cite NAS and BPC as authorities for establishing the existence of "the problem," but they do not define "the problem" the same way. The NAS formaldehyde review scrupulously avoids clearly stating what the problem is, and the definitions in each of the general NAS risk assessment tomes tend to be different--sometimes subtly so, sometimes starkly. And the BPC views "the problem" very differently than you appear to do.

Here is a suggestion for a working definition of "the problem":

(A) Policy officials reaching into and attempting to influence or control the realm of science (i.e., what is).

(B) Scientific staff reaching into and attempting to influence or control the realm of policy (i.e., what ought to be).

The Obama Scientific Integrity memo lies squarely within this category, but of course it was issued before the administration had any experience with governing. Once can only imagine what its authors believe now. Could you interview them? Would they answer your questions candidly? How would you know? The BPC report lies mostly within this category because many of its members are people with extensive experience in governing. One suspects that before government service they thought (A) was "the problem" and now they think (B) is "the problem." Could you interview them? Would they answer your questions candidly? How would you know?

Your outline seems to be oriented toward making (A) more transparent. If that is your intent, then be clear about it and state up front that you are have no brief for making (B) more transparent. If that is right, then your search should be directed solely to purported examples of (A), but with much greater effort devoted to validating that they really were examples of (A) and not examples of (B) in disguise.

Dr. Richard B. Belzer

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Re: Science in the Administrative Process [message #45 is a reply to message #35]

Wed, 23 November 2011 16:11

Richard B. Belzer
Messages: 4
Registered: November 2011
Location: Mount Vernon, VA

Interagency coordination and transparency are competitors. The former cannot coexist with the latter. Case in point: Written communications between OMB and EPA on NAAQS rulemakings must be included in EPA's docket. The practical consequence is sensitive communications are shifted to the telephone. Therefore, to the extent that interagency coordination is a "solution" to "the problem" (which is still not clearly defined) it will reduce transparency rather than increase it.

There is an equilibrium (and low) level of transparency in interagency coordination. Any effort to increase transparency one place will be countered by a reduction elsewhere.

Dr. Richard B. Belzer

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Re: Science in the Administrative Process [message #46 is a reply to message #36] Wed, 23 November 2011 17:00

Richard B. Belzer
Messages: 4
Registered: November 2011
Location: Mount Vernon, VA

From Peter Strauss: "[T]he proposal now is about the difference between what is conventionally described as risk/science assessment and risk/science management."

Perhaps, but version (B) of "the problem" (as I referred to it in my reply to Wendy's initial post) posits that there is a lot of policy lurking in "risk assessment." And we know this to be true, for the EPA staff has said so clearly:

Quote:

> EPA's policy is that risk assessments should not knowingly underestimate or grossly overestimate risks.

See EPA Office of the Science Advisor, "Examination of EPA Risk Assessment Principles and Practices," 2004, p. 13 (http://www.epa.gov/osainter/pdfs/ratf-final.pdf).

This means the *EPA staff* have a policy preference for erring on the side of overstating risk (just not "grossly") and an explicit determination NOT to estimate risk in an unbiased manner. This is a risk management choice embedded in a risk assessment. What justification does the EPA staff offer for this practice? It's because "EPA is a health and environmental protective agency." (Id.) Does Congress require this? EPA says so (pp. 13-16), but every example given concerns a Congressional risk *management* preference.

I've yet to see a single case in which Congress has directed EPA (or any other agency) to base decisions on biased estimates of risk. Consider the most famous (and perhaps most contentious) of these directives -- the requirement to set criteria air pollutant standards that "protect public health with an adequate margin of safety" without regard to cost per *Whitman v. American Trucking*. Does the CAA direct EPA to estimate health risk in a biased manner? No. In fact, it forbids this. Section 108(a)(2) requires that air pollution criteria "*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."

Accurate is a synonym for *unbiased*.

Dr. Richard B. Belzer

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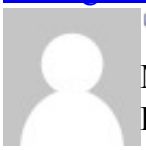
Re: Science in the Administrative Process [message #47 is a reply to message #43] Fri, 25 November 2011 13:15



Susan Dudley (ACUS)
Messages: 2
Registered: November 2011

Thanks for your quick response, Wendy. I don't think noting the distinction between science and policy judgment in the introduction will be sufficient.

I appreciate that it is difficult to separate science from policy, but that should encourage extra vigilance throughout the study, in identifying issues, conducting research, and offering recommendations. Richard Belzer (in post #43) offers a useful classification of the problem into 2 types: A) where policy officials attempt to influence the realm of science and B) where scientists attempt to influence the realm of policy.

Section I of the proposed outline highlights several key issues without mentioning problem type B, despite the BPC's conclusion that the "tendency to frame regulatory issues as debates solely about science, regardless of the actual subject in dispute, is at the root of the stalemate and acrimony all too present in the regulatory system today" (BPC, 11).

Without recognizing the policy nature of many of these choices, issue I.B of the outline, for example, ("continuing challenges in protecting the scientific independence of government scientists and protecting against the politicization of science") may serve to reinforce the blurring of the line between science and policy by labeling as "politicizing" disputes over policy choices. Using Belzer's classification, you seem to presume the problem is A, and by doing so may exacerbate B. This is important, because according to the BPC report, "some disputes over the 'politicization' of science [Belzer's type A problem] actually arise over differences about policy choices that science can inform, but not determine." (BPC, 4)

Without a clearer distinction between what science can inform but not determine, issue I.C (asserting that science advisors are under-utilized) also seems overly broad. Note that BPC recommended that "scientific advisory panels should not be asked to recommend specific regulatory policies."(BPC, 5)

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Follow-up to Dudley post dated November 25 [message #48 is a reply to message #47] Fri, 25 November 2011 15:47

Richard B. Belzer
Messages: 4

Registered: November 2011
Location: Mount Vernon, VA

Wendy,

Greater reliance on science advisors might be a good remedy for Type A of the problem, but it's a dubious remedy at best for the Type B version. Here's a great example, one that I bet Susan remembers all too well.

After EPA Administration Johnson selected 0.075 ppm for the ozone NAAQS in 2008, CASAC was mighty unhappy. The committee sent him an unsolicited letter containing, among other things, the following sentence:

"It is the Committee's consensus scientific opinion that your decision to set the primary ozone standard above this range fails to satisfy the explicit stipulations of the Clean Air Act that you ensure an adequate margin of safety for all individuals, including sensitive populations."

See http://yosemite.epa.gov/sab/sabproduct.nsf/4AF87643243312888 52574250069E494/$File/EPA-CASAC-08-009-unsigned.pdf

This is a clear example of scientists attempting to reach into and influence or control the realm of policy. CASAC's statement is demonstrably false becauae there is no conceivable *scientific* definition of an "adequate" margin of safety. CASAC was expressing its consensus *policy* opinion in an extraordinarily disingenuous (though perhaps unwittingly transparent) way.

Each member of CASAC was entitled to have (and express) a view about policy. But CASAC was never entitled to misrepresent its *policy* views as *science*. Tragically, by making such a brazen claim of *scientific* authority, CASAC gravely damaged its own credibility as a *scientific* peer review body.

It is impossible now to read any of CASAC's reports and discern where its scientific review ends and its policy advocacy begins. EPA Administrators who have different policy views now must risk "interfering with science" to reclaim the authority delegated to them by Congress. EPA Administrators who agree with CASAC on policy face no such political challenge; they can disingenuously claim that they are merely upholding science.

This is why the selection of CASAC members (and peer reviewers generally) has become so controversial. The ability to choose the "scientists" is tantamount to choosing what policy advice to receive.

And this gives us a new Type C version of the problem: policy officials abdicating their statutory authority (and responsibility) to make policy decisions by hiding behind "science"--I.e., allowing scientists to reach into and control policy decisions because it is politically expedient.

Dr. Richard B. Belzer

Re: Follow-up to Dudley post dated November 25 [message #49 is a reply to message #48] Mon, 28 November 2011 13:35

Wendy Wagner (ACUS)
Messages: 6
Registered: October 2011

Rick and Susan,

Thank you for your comments. I think we've fallen a bit off track with respect to the focus of this study, however. The intent of this first, general study is to explore how well the agencies explicate the role that science plays in regulatory decisions (e.g., literature reviews, how they weight studies, the processes they use for analyzing the relevant literature, external oversight mechanisms, etc.; see the list of questions in part IIC). This focus on how well the agencies explicate science is by no means an easy job, but it is a whole lot easier methodologically than trying to identify why there may sometimes be a lack of transparency or blurring of science and policy (e.g., Rick's hypotheses a through c, plus many other possible causes, such as agency staff inadvertence and even incoherence). Remember too that this study is likely the first of likely many studies on regulatory science. Others from ACUS or outside of the government can later explore why the agencies might not explicate the role of science well in some settings, if there are problems with this first-level explication. Subsequent investigators can also study the science advisory process in detail (e.g., selection of members, points of controversy) as well as the costs and benefits of smoother interagency coordination on regulatory science.

Susan requests a more elaborate examination of some of the issues listed in Section I; but this section is not the focus of the study. Section II describes the focus of the study. Section I provides only background and is intended to offer an impressionistic sense of the larger science-policy landscape within which this narrow study is situated.

For purposes of the study, I will interview staff not only in the four agencies under investigation, but also staff in OSTP, OMB, NAS, and a range of stakeholders that include industry and public interest groups. Rick is correct that OMB, as well as these other staff, are important resources for the study. The list of interviewees should have been included in the outline; I apologize for this omission.

Thanks again for your comments. All the best, Wendy

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Re: Science in the Administrative Process [message #50 is a reply to message #34] Mon, 05 December 2011 12:41

Jamie Conrad

Messages: 1
Registered: December 2011
Location: Washington DC

Wendy

You have done a great job refocusing this initial ACUS study of science in the administrative process--not only is the scope a lot narrower than what you initially proposed in May, but you're addressing an issue that is centrally important both in its own right and, as you correctly note, for its ability to shed light on other important issues. The NAS Formaldehyde report and the White House scientific integrity memoranda do highlight a fundamental and widespread problem: agencies often do not clearly explain how they are using science. On the other hand, if they were clearer they would, among other things, make it easier for external entities to evaluate and police that usage. Of the following observations and suggestions, some are directed toward improving your proposal and others are intended to reinforce what you have already said. These comments derive primarily from your outline, but also reflect some prior posts in this forum.

1. Can you do this alone?

Much as I agree with your choice of issue, I have some reservations about the ability of your proposed method to generate really informed and reliable findings regarding the adequacy of agency explanations of their use of science. I know you have a BS in Biology and have toiled in regulatory-scientific vineyard for your whole career. But the scope of your study is essentially a broader version of what the NAS Formaldehyde panel took it upon itself to do: critiquing how well agencies explain their scientific reasoning. I am concerned that one would need to be, or have access to, a scientist with some qualifications in the relevant field to do this well and feel confident that you were not being snowed by an agency that says it's doing a good job. (In many cases, agencies have guidance for various types of analyses and say they follow them. Serious claims are often made that they don't, and adjudicating these claims can require sophisticated expertise.) I'm not seeking to torpedo the project, only to raise the issue for further consideration.

2. Information gathering processes

In your outline, you note that a clearer statement of how an agency used science "provide[s] a more accessible view of what research has been done and what hasn't" and "invites a broader range of stakeholders into the process." In your post #37, you also highlight the information-gathering process that EPA uses at the commencement of each NAAQS revision. The National Academy of Sciences (BEST, at least) generally begins each new study with a day or half-day open session where stakeholders are invited to engage with panelists to discuss the state of the relevant science, including the major unanswered questions and most significant work to date. I would urge you to look carefully to see whether and how agencies use some sort of process like this at the outset of an initiative to make maximum use of external expertise and to clarify issues and questions as fully as possible. I'm attaching a comment that I filed with EPA's Science Advisory Board this summer in connection with its recent review of public participation processes. On pages 6 and 7-11, I describe a proposed process for this kind of early information-gathering. I have to think that it could generate enormous savings in time and improvements in quality.

3. Your "show your work" questions

I generally endorse the list of questions under § II.C of your outline, and offer these additional comments:

- *Overall.* While it only applies to risk assessments conducted by EPA, probably the best single source of questions or considerations relevant to evaluating how well scientific assessments have been explained is the EPA Science Policy Council's Risk Characterization Handbook. Here's a link:

http://www.epa.gov/spc/pdfs/rchandbk.pdf

- d. *"How the agency then used the relevant studies and weighted them?"* I think this question warrants some unpacking. The central issue is whether the agency has articulated, in the words of the NAS, (i) "clear and concise statements of criteria used to exclude, include, and advance studies," involving "standardized approaches that are clearly formulated and based on the type of research," and (ii) "rationales for the selection of studies" that involve "rigorous and systematic coverage of the various determinants of weight of evidence." In each case, two things are at issue: (i) has the agency stated a clear decision framework, and (ii) has the agency actually explained how it applied that framework?

- e. *"How the agency incorporated (or at least discussed) applicable, cutting edge methods and technologies or other bodies of evidence that interface with regulatory decisions?"* This is important, because I think agencies are generally lagging indicators of scientific progress. Here or elsewhere, you should ask whether the agency has considered competing models and hypotheses. For example, probably the single greatest source of delay in EPA's evaluation of the carcinogenicity of chemicals, including formaldehyde, dioxin, and chromium VI, has been EPA's dismissal of nonlinear mechanisms of action--which the NAS or SAB has then criticized, leading to additional rounds of analysis and review.

- f. *"The timing of the agency's assessment of the science in light of the policymaking features of the decision."* A related timing question is whether the agency has constructed its timetable to take advantage of privately-funded research that addresses important questions or uncertainties. I am well aware that this sort of work is commonly viewed as being conducted to "manufacture uncertainty." However, in my experience companies have been spending great sums of money to conduct tests pursuant to agency test guidelines and GLP rules aimed at answering key questions. In the absence of a public health emergency or reason to doubt the legitimacy of the outside work, and assuming that work is being done with reasonable dispatch, for an agency not to take it into account suggests to many that it had a preconceived outcome that it did not want upset by potentially inconsistent findings.

Some other potential questions:

- *Has the agency explained whether it has used the best available science?* E.O. 13563 says: "Our regulatory system . . . must be based on the best available science." As you note in post #34, clearer explication should make it easier to evaluate whether this is happening.

- *Has the agency identified and discussed the major uncertainties in its analysis and their potential effect on its conclusions? See* EPA Risk Characterization Handbook at 15-16.

- *Has the agency identified and provided rationales for its use of judgments (e.g., assumptions and defaults)? See* OMB's Updated Principles for Risk Analysis (2007) at 8 (available at

http://www.whitehouse.gov/sites/default/files/omb/assets/omb /memoranda/fy2007/m07-24.pdf)

- *Has the agency consulted with outside sources of expertise at the outset of the effort and at other appropriate junctures? See* my point about "information gathering processes" above.

4. "Politicization"

I am glad that Peter has flagged (his posts # 36 & 39) and you've recognized (your post #40) the need to encompass within "politicization" the ability of senior career staff (rather than only political appointees) to suppress or misrepresent the scientific work of the staff they supervise. By virtue of their authority and longevity (in contrast with politicals, who they can outlast), senior career staff can have enormous influence on agency scientific processes and positions.

It is also important to recognize, as the BPC report and Susan Dudley (post #47) have noted, that some "politicization" actually reflects disagreement over policy choices that our system charges political appointees with making.

5. Future work

I like your list of "other issues that deserve attention in the future" (§ I). Some observations:

- There is a lot of concern about the competency with which agencies use science in various settings. ("Transparency" ought to be addressed in this study, though, right?)

- There is a great deal of variation among and even within agencies regarding their use of review processes. Use of contractors to organize panels (thus evading FACA and ethics rules) is a chief problem; inconsistent application of ethics rules is another.

- I agree that there is a discouragingly low level of cross-fertilization and coordination among agencies on projects and methods.

- I still am not clear what distinction you are making between "science-advisors" and "advisory boards"--the latter seem to me a subset of the former.

Best,

Jamie

- Attachment: SAB Public Involvement Comments.pdf
  (Size: 163.12KB, Downloaded 62448 times)

[Updated on: Tue, 06 December 2011 08:48] by Moderator

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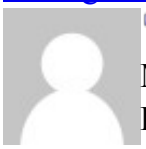
Re: Science in the Administrative Process [message #51 is a reply to message #50]

Fri, 09 December 2011 15:12



Wendy Wagner (ACUS)
Messages: 6
Registered: October 2011

Jamie,

Thank for your comments. They are very helpful. I agree that, even with considerable narrowing, the study is still relatively ambitious, although I do not believe it is as ambitious as you suggest. The study will examine the processes and manner by which the agencies explain how science informed their regulatory decisions. Precisely because I am not a NAS panel w/ 2-3 years to study how the EPA handled one individual toxic substance, I cannot begin to review the substance of the agencies' analyses. However, I can judge whether agencies are generally offering some accessible/coherent-sounding explanations for how they reviewed the literature, weighed the uncertainty, etc. within categories of regulatory programs. Your questions in #3 at first blush seem fall into that "did the agency explain this or that?" category, but many of your questions (e.g., whether the agency has stated a clear decision framework) are much more substantive and detailed than I believe can be addressed in this initial study. More to the point, I worry that these more specific questions will require mastery of the intricate details of individual rules and ultimately explode the study into one that is far more extensive than originally envisioned. Such detailed inquiry also requires a high level of scientific sophistication and a level of expertise that you rightly suggest I lack (although I do have a little more scientific education than you suggest -- a masters from Yale and the start of a PhD at U. of Virginia in envtl. sciences.). So I will do my best to consider these questions and agree they are important, but it is likely that most will have to await a subsequent study. In contrast, your BEST suggestion in part 2 of your post is exactly the kind of innovation that I can use for this study, so please pass along other similar suggestions as they come to you.

In response to your question about "science advisors" vs. "advisory boards" (in Part 5), for the former I was referring to the official person in some agencies who is designated as a "science advisor" (a position that is usually but not always appointed). Agencies like FDA and EPA have this science advisor position. There was even a science advisor to the AG for a while. This strikes me as an interesting innovation that may be worth studying in the future. Imagine how such a position could improve interagency coordination/communication, for example, if OSTP convened regular meetings of the agencies' science advisors. Regrettably, though, this feature is beyond the scope of my study; I simply intend to flag it for future research.

Again, thanks for your questions and suggestions. They are very useful in sharpening and refining the study's approach and goals. All the best, Wendy

Report message to a moderator

profile pm

Re: Science in the Administrative Process [message #52 is a reply to message #31] Thu, 15 December 2011 12:10

pldelacruz
Messages: 1
Registered: December 2011
Location: Washington, DC

Wendy,

I very much appreciate your work on this important topic and the ability to read through the forum discussion. Comments are attached and I would be happy to discuss them or respond to any questions they might raise.

Thanks,
Peter

- Attachment: SIRC - ACUS Science in Admin Process 2011-12-15.pdf
(Size: 120.55KB, Downloaded 62739 times)

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Re: Science in the Administrative Process [message #53 is a reply to message #52] Mon, 19 December 2011 11:21

Reeve Bull (Staff)
Messages: 6
Registered: September 2011
As of December 15 at 5:00 pm, the forum will no longer accept additional postings; it will, however, remain available in a "read only" format to allow interested users to read the postings submitted during the meeting. Please direct any inquiries to Staff Counsel Reeve T. Bull at rbull@acus.gov.

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Appendix A

"Science in the Administrative Process": Take 2
Draft Outline 10/30/2011

Wendy Wagner, University of Texas School of Law

General Description and Focus of the Study

Reform proposals offered over the last decade to redress perceived problems in regulatory science generally target one of two points in the agencies' decision-making process. One set of reforms seeks to shore up internal oversight of science within the agencies, including strengthening how agency staff and political officials assemble, weigh, and communicate the scientific information used in their regulatory decisions. A second set of reforms attempts to reinvigorate external checks on agency decisions that involve scientific information (e.g., greater White House review, less deferential judicial review, more points for interest group input, and greater congressional oversight).

This study focuses on a specific topic within the first set of reforms -- strengthening internal agency processes for communicating how it uses science for regulation -- rather than on bolstering external checks on regulatory science. Improvements in the agencies' internal procedures for explicating how it uses science will not only facilitate better use of science from within the agency, but will spill over to enhance external oversight mechanisms as well. If the agency does a better job of explaining its work, for example, it will be easier for outside parties to ensure that the agencies' use of science comports with the authorizing law, the larger scientific record, and political preferences. Considerable attention has also been focused within the Obama Administration on improving the transparency of the agencies' use of science for regulation.

I. Science in the Regulatory Process: The Larger Landscape

The vastness of the topic of "science in the administrative process," plus the tremendous variation between agencies, make it practically impossible to understand how agencies use science in anything close to a comprehensive way. The best that can be done is to explore parts of the administrative state with the obvious risk that the problems most in need of attention have been missed.

This introductory section endeavors to identify the general issues that emerged from agency interviews, documents, and the literature in the course of the study regarding problems involved in the agencies' use of science. This preliminary map of the larger set of issues should be helpful not only to situate the study within the larger terrain, but also to spotlight a host of other issues that deserve attention in the future.

A. There is very little cross-fertilization and coordination between agencies on overlapping science-based projects (e.g., the use of computational models; risk assessments).
B. There are continuing challenges in protecting the scientific independence of government scientists and protecting against the politicization of science (both intentional and inadvertent).
C. There is under-utilization of science-advisors as independent resources for science advice.

D. There is considerable variation (not all for the good) in the scientific review processes used by different agencies (e.g., FACA advisory boards; peer review processes).
E. There are concerns with respect to how the agencies use science in various settings (e.g., transparency, competency).
F. There are challenges in hiring and retaining qualified scientists, particularly those well-versed in emerging technologies, to serve in government.

II. Focus of this Study

Regulatory science is often under fire, particularly when agency decisions are hotly contested. Perhaps for that reason, the agencies have sometimes been opaque about how they use science in their regulatory projects. It can be difficult to identify how the agency actually did its literature search, ascertain what choices it made in relying more heavily on some studies and not others, and isolate other assumptions adopted by the agency. As a result, those outside (and even inside) the agency must expend considerable time and effort reconstructing the agencies' analysis by working backwards from the regulatory result.

Over the last few decades, federal agencies have been criticized repeatedly for not being clear about the role that science played in their decision-making process. A number of efforts have been made by the Executive Branch to redress this perceived problem.[1] Specifically, President Obama issued a letter to the agencies directing that "To the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking."[2] This directive was further elaborated by the Director of OSTP by directing agencies to "communicate scientific and technological findings by including a clear explication of underlying assumptions; accurate contextualization of uncertainties; and a description of the probabilities associated with both optimistic and pessimistic case projections . . . ".[3]

This study explores how well the agencies have done and are doing in terms of explicating the role that science plays in their regulatory decisions. Are there significant lapses in the agencies' explanation of how they use science? Are agencies changing their practices in light of the recent White House directives to increase the transparency of the role science plays in the regulatory process?

A. Central Justification

There are a number of reasons that this particular issue is worthy of study as the first in a series of ACUS studies on regulatory science.

1. *Evidence of a problem.* This problem has been identified as one in need of reform by bipartisan, respected organizations like the National Academy of Sciences[4] and the

[1] *See* Section II.A.1., *infra*.
[2] Obama letter March 2009.
[3] OSTP Memo (2009).
[4] *See, e.g.*, National Research Council, Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde (2011); Committee on Risk Assessment of Hazardous Air Pollutants, National Research Council, Science and Judgment in Risk Assessment (1994); National Research Council, Risk Assessment in the Federal Government: Managing the Process (1983)

Bipartisan Policy Center.[5] Recognition of the problem has also been a recurring theme in some of the judicial reversals of agency science-based regulation.[6] Both the Obama and Holdren memoranda on scientific integrity, as mentioned, also identify the need for greater transparency in the agency's use of science. Yet, there is not much specific evidence of the extent of this problem within government.

2. *Central Role in Accountable Regulation.* A clear explication by the agencies of how science is used improves the quality of scientific oversight, the quality of policy deliberations, and increases the accountability of regulatory agencies. None of the other potential topics discussed in part I is as fundamental with respect to ensuring the integrity of regulatory science.
3. *Limited incentives for transparency.* Despite the centrality of the principle that agencies should "show their work" when it comes to science, there are a number of institutional incentives that might reward agencies for actually being quite opaque about the role science plays in decision-making, at least in some program areas. Yet other than judicial remands for failing to explain a decision, the agencies face few penalties for failing to provide a succinct and clear statement of how scientific information informs their work.
4. *Expected prevalence of the problem across agencies.* While the bulk of the reported problems in the agency's explication of science occur within EPA and to some extent DOI, there are reasons to believe that these same problems sometimes occur in other agencies. Examination of this problem in other agencies will advance understanding of regulatory science and likely spotlight other, related problems that deserve attention in the future.
5. *Amenable to Reform.* Unlike some other systemic problems – e.g., lack of interagency coordination – providing stronger incentives for agencies to provide a clearer explication of the role science plays in their decision is a process-based reform that seems, at least in the abstract, to be capable of implementation. Moreover, the considerable interagency variation in the use of science provides reason for optimism that a "better way" may already be instituted in some regulatory programs that can serve as models.

B. Additional Benefits

Understanding and, if needed, redressing the agencies' explication of the role of science in their decisions, is so central to administrative process that it also lays the foundation for reform of other, related problems:

1. Clearer statements of how the agency used science will provide the courts with a record for reviewing what the agency has done and reduce the risk of judicial challenge. The agencies' failure to explain their work is one of the most common bases for remands.[7]

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[5] Bipartisan Policy Center, Improving the Use of Science in Regulatory Policy 15-16, 41-42 (Aug. 2009); *see also* Advancing the Public Interest through Regulatory Reform: Recommendations for President-Elect Obama and the 111th Congress, c/o OMB Watch 26, 34, 47 (Nov. 2008).

[6] For an early example, *see Ethyl Corp. v. EPA*, 541 F.2d 1, 68 (D.C. Cir. 1976) (Bazelon, concurring) ("It is not enough for an agency to prepare a record compiling all the evidence it relied upon for its action; it must also organize and digest it, so that a reviewing court is not forced to scour the four corners of the record to find that evidence for itself. . . . . In informal rule-making, the record should clearly disclose when each piece of new information is received and when and how it was made available for comment.")

[7] Nearly forty percent of the vacaturs of agency regulations apparently occur because the agency failed to adequately explain or document its reasoning. *See, e.g.*, Patricia M. Wald, *Judicial Review in the Time of Cholera*, 49 ADMIN. L. REV. 659, 665 (1997); *see also* Christopher H. Schroeder & Robert L. Glicksman, *Chevron, State Farm and*

2. Clearer statements of how the agency used science in advance of OMB review could provide a bulwark against allegations that OMB changed (or will change) the substance of the agency's technical analysis.
3. There are concerns that the agency does not always use cutting edge methods and techniques, including more sophisticated use of social science, or that it does not use several alternative models/techniques to illuminate the scientific uncertainties. If the agency clearly states its methods for searching the literature and the studies it relied on, future research discoveries and alternate approaches could be integrated into the regulatory project more effectively.
4. Clearer statements of the agency's use of the available science could facilitate better inter-agency coordination since agencies could isolate points of disagreement more expeditiously.
5. Clearer statements of the agency's use of the available science will provide a more accessible view of what research has been done and what hasn't, and the quality of the research that is available. Such a clear statement thus identifies the most promising areas for future research, invites a broader range of stakeholders into the process, and highlights when the agency may have very little research available for carrying out its mandate, which in some settings will justify precautionary action.
6. Requiring agencies to explain the role science played in their regulatory decisions helps deter politicization of science and impedes the ability of stakeholders to drag agencies down into distractions or debates over the almost infinite ways that the scientific literature could have been weighted differently. Explication thus serves to focus and narrow the issues in dispute.
7. When a researcher publishes a review article that summarizes the research, he or she must include a methods statement of how he or she used the literature: At the very least, when an agency is using science, it should follow these same, well-established scientific practices.

C. Methods and Design

This study will focus on four agencies that use science extensively in their regulatory decision-making: EPA, FDA, NRC, and DOI. EPA and FDA are high profile and often controversial users of science. DOI is also a high profile agency, but its issue areas are environmental and natural resource protection rather than public health protection. NRC is an independent agency and thus provides a point of departure with respect to Executive Branch oversight. The study is limited to four agencies because of limited time and resources.

Each of these agencies will be studied by seeking relevant documents from within the agencies that pertain to their methods for explicating the use of science; through interviews with agency staff (past and present) and knowledgeable stakeholders; and reliance, where appropriate, on other government-related studies by NAS, OTA, GAO, and the general literature.

The following general questions will be explored in this research: Do agencies currently "show their work" in explaining how they searched the literature and how they used the available studies/literature? For example, do the agencies explain:

a. The question(s) in need of scientific guidance?
b. How they searched the scientific literature?

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the EPA in the Courts of Appeals in the 1990s, 31 ENVTL. L. REP. (ELI) 10371, 10405 (April 2001) (describing a decade of cases in which EPA rules were remanded for failure to support the agency's reasoning).

c. Whether all the relevant literature was included and made available to the public to the extent possible, including internal information and confidential information?
d. How the agency then used the relevant studies and weighted them?
e. How the agency incorporated (or at least discussed) applicable, cutting edge methods and technologies or other bodies of evidence that interface with regulatory decisions?
f. The timing of the agency's assessment of the science in light of the policymaking features of the decision?
g. The agency's ability to revisit the decision at regular intervals as the science changes?

III. Findings

A. Agency Successes in Explicating and Using Science for Regulation
[tbd]

B. Evidence of Problems
[tbd]

C. If/when the agencies don't do a good job showing their work, why not? Are there barriers/requirements/other impediments to communicating how they used the relevant science?
[tbd]

IV. Reform Recommendations [a *very* preliminary sketch, which is a placeholder for tbd]

Reforms will hopefully draw on advances already made by some agencies. Some recommendations could include:

1. Explanation of the Scientific Evidence Considered (including Literature Search Methods, etc.)

In cases where internal agency staff provides some of the basic scientific evidence that informs decisions, this research must be included in the decision and made publicly available.

2. Explication of the Agency's Assessment of Studies, its Assumptions, and its Methods of Analysis

The agencies should be encouraged to follow the NAS Formaldehyde Report (chpt. 7) and provide a clear, concise statement of how they reviewed the relevant scientific literature; identify the studies they included/excluded and why; and explain how they weighted and critiqued the studies. Ideally, these "methods for integrating science in a regulatory decision" would be captured in government-wide or at least agency-wide general guidances that provide a general set of rules. Then, in individual regulatory projects, the agency would apply the guidance and be explicit in its use of science in case-specific settings.

a) Authorship of the Scientific Assessment

An assessment that explicates the role that science plays in a regulatory decision should be developed by the agency's experts.

b) Timing/Process of the Assessment

A statement that explicates the role that science plays in a decision should be prepared before a proposed rule is published since it informs the agency's view of the literature, much like EPA's integrated science assessment for NAAQS.

c) Form of the statement

The scientific assessment should be succinct and clear, following the recommendations in the NAS Formaldehyde report. The basic assessment should be published, in full or part, in the preamble of the proposed rule, although it would not be subjected to notice and comment separately from the proposed rule.

3. Incentives for Doing a Good Job Explicating the Role of Science

Recommendations for a clearer explication of the role of science operates in a realm where agencies are already suffering from multiple, demanding analytical requirements and operating on thin budgets. A critical feature of these recommendations is to identify ways that a clear explication of the role of science can replace other, largely duplicative analytical requirements so that the recommendation ultimately lightens, rather than burdens the agencies' workloads.

Interview Protocol (tailored depending on interviewee)

Explicating How Science is Used in Regulatory Decisions

1. If you are familiar with the NAS's recent Formaldehyde report (2011), do you have a sense that _____ struggles with some of these same difficulties in explicating the role that science plays in a regulatory decision?
   For example, does ____ have general or program-specific guidelines that direct staff to provide an accessible and succinct explanation of how it used science in its decision (e.g., how the agency conducted the evidence/literature search; the inclusion/exclusion criteria for studies; how the various studies were weighted; explication of assumptions (particularly policy-based) and uncertainties; a candid discussion of challenges in incorporating certain cutting-edge evidence or methods into the analysis)?
2. If there is a formal or informal protocol at _____ for this clear explication of science, does this type of integrated science assessment occur early in the decision-making process, largely prior to the policy-making stages? If so, is this science assessment publicly available? And is the assessment reviewed at regulator intervals (e.g., every five years) or when the science advances significantly?
3. If _____ doesn't have general guidance or policies directing _____ staff to explain their use of science, would such guidance be helpful (e.g., guidelines that direct staff to explain succinctly and in ways that can be replicated how they did the literature search, weighted studies, reached assumptions, and even instructions regarding the timing of preparing and publishing of such an assessment)?

Scientific Freedom of Staff

4. Are there assurances of scientific freedom to ___'s staff. What has ____ done to comply with the recent Holdren memorandum on this issue?

Inter-agency Communications and Collaborations

5. Does OMB play a role in _____'s evaluation of the scientific literature and its description of how that literature affects its resulting regulatory decisions?
6. Is there much inter-agency coordination between _____ and other regulatory agencies? For example does your office meet w/ the Department's Science Advisor periodically?
7. What effort has _____ expended to ensure that it is making good use of emerging technical and scientific discoveries? Are there approaches/methods that _____has pioneered that can be easily grafted over to other agencies struggling with the same challenges?

Appendix B

6

Possible Controls over the Bending of Regulatory Science

PETER L STRAUSS*

INTRODUCTION

'BELLEROPHON TAMING PEGASUS', the monumental statue shadowing the formal entrance to Columbia Law School, states in metaphor the tension that motivates this piece. Nominally it reflects reason taming unreason, which is the role that law claims in society. One knowing a bit of its history sees more. Commissioned in the early 1960s, its earliest sketches reflected a proportion and a distance between man the master and the winged horse of unreason suggesting optimism that the outcome was secure. The golden bridle would do its work and reason would prevail. As the early 1960s became the late 1960s, Pegasus grew in the sketches, Bellerophon shrank, and ultimately the two merged. Now Pegasus was Bellerophon's own head; the bridle was around his own neck; the horse's expression of pain and rage was his own. And as Bellerophon could never completely tighten the noose around his own neck if he wished to live, one knew that the struggle could not be resolved. Reason and unreason continuously contend. What a metaphor for the project of law!

In particular, what a metaphor for the continuing tensions between objective ('scientific') and political inputs to regulatory decision-making. For science as for law, the ambition is for 'reason', for analysis as free as it can be of the influence of 'man'. Here's a strong statement of that position, that might be taken as scientists' equivalent of 'government of laws and not of men'.

> Science is, and can only be, descriptive and explanatory. Whether a scientific finding is judged to be accurate is dependent on the quality and rigor of the methods used and

* Betts Professor of Law, Columbia Law School, Columbia University, New York, NY. This chapter, first shown in draft to the conference on global administrative law in whose volume it appears, has gained much from colleagues at the European University Institute, the Universities of Sydney, Melbourne, Victoria, and Auckland and the Australian National University, where I was privileged to visit and present it, and also from able research assistant, Andrew Amend, Columbia 2008. It remains very much a work in progress, during changing times.

> whether that finding is replicable. The scientific process is not democratic—no amount of desire for different results can establish them—and inconsistent findings create true controversy only when their methods are of comparable validity.[1]

Of course it is equally futile. For science as for law, 'man' *cannot* be eliminated. Judgements must be made in inevitable arenas of uncertainty—judgements that will be shaped by human predispositions and heuristics that need hardly correspond to the realities they seek to describe. And beyond these unavoidable human difficulties lie the incentives that in so many contexts twist human behaviours in ways that law seeks to control—greed for profit and lust for power central among them. The issue, then, is somehow giving the objective or perhaps one should just say the open side of scientific endeavour purchase—elevating judgement, suppressing simple will.

The American regulatory landscape has been littered with efforts to distort or suppress information relevant to the responsibilities of federal agencies responsible for protecting health, safety or the environment on the basis of sound science. While these efforts have a long historical pedigree—consider the industrial practices respecting such hazards as silicosis, tobacco and asbestos, or government behaviours in respect of nuclear weapons testing[2] or the Tuskeegee experiment[3]—recent times have seen them take particular prominence. Drug company failures to, for instance, alert regulators respecting hazards created by their products spread across the pages of two recent books describing a variety of means that have been used in the service of distorted outcomes: creation of research to produce intended outcomes; suppression of unwanted information; discrediting reliable research; interfering with the careers of those who produce unwanted information; and public relations campaigns.[4] 'The editors of our best international scientific and medical journals', one reports, 'are chagrined by their inability to weed out unreliable research emerging from a funding regime that is increasingly driven by the expectation of future economic gain.'[5] Within the science community, they suggest, organised insistence on recreating the conditions for honest inquiry will require such measures as mandatory disclosures of all financial interests (conflict of interest reporting) and the development of techniques for data-sharing that permit peer review while diminishing opportunities for harassment and other inappropriate behaviours—along with vigilant self-policing regimes. The situation, one might say, reflects only an ordinary

[1] JD Kraemer, LO Gostin, 'Science, Politics, and Values**:** The Politicization of Professional Practice Guidelines' (2009) 301(6) *Journal of the American Medical Association* 665–67 available at www.jama.ama-assn.org/cgi/content/full/301/6/665.

[2] www.hss.energy.gov/healthsafety/ohre/roadmap/experiments/index.html; www.historytogo.utah.gov/utah_chapters/utah_today/nucleartestingandthedownwinders.html.

[3] www.cdc.gov/tuskegee/timeline.htm.

[4] TO McGarity and WE Wagner, *Bending Science: How Special Interests Corrupt Public Health Research* (Cambridge MA, Harvard University Press, 2008); D Michaels, *Doubt is Their Product: How Industry's Assault on Science Threatens Your Health* (Oxford, Oxford University Press, 2008).

[5] McGarity and Wagner, n 4 above, at 229–30.

instance of a particular community's need to identify and suppress deviant behaviours that threaten its integrity and values. Theft and fraud, too, are social problems and we develop law and institutions to secure our sense of social honesty. But it is not, of course, simply an intra-community affair. The public consequences of distortion may be quite severe.

Similar alarms were widespread about the Bush administration's treatment of scientific issues. In what one journalist-reporter characterised as 'The Republican War on Science',[6] battles ranged over such disparate issues as global warming, day-after contraception, endangered species protection, environmental hazard regulation and politicised controls of advisory committee membership. Sixty-two prominent scientists issued a remarkable call for 'Restoring Scientific Integrity in Policy-Making' in February of 2004.[7] Thousands more signed it subsequently, and the signatories included 52 Nobel laureates, 63 National Medal of Science recipients, and 195 members of the National Academies.[8] A more recent journalist's account, 'Undermining Science: Suppression and Distortion in the Bush Administration',[9] suggested that little changed in its wake.

Politics certainly infected these alarms. The Union of Concerned Scientists, that catalysed both the petition and the more recent book, is not a neutral body. Conservative authors and columnists have persuasively pointed to similar episodes in Democrat administrations,[10] and the literature on science, policy and

[6] C Mooney, *The Republican War on Science* (New York, Basic Books, 2005).

[7] The text can be found on the website of the Union of Concerned Scientists, www.ucsusa.org/scientific_integrity/abuses_of_science/scientists-sign-on-statement.html.

[8] www.ucsusa.org/scientific_integrity/solutions/big_picture_solutions/prominent-statement-signatories.html.

[9] S Shulman, *Undermining Science: Suppression and Distortion in the Bush Administration* (Berkeley and Los Angeles, University of California Press, 2008).

[10] 'For the sake of argument, let's assume that the Bush administration has done all that UCS accuses it of doing. This problem is not particular to Republican administrations—the very linkage of government and science almost guarantees some chicanery. Let's recall the halcyon days of the Clinton administration. In 1993, Princeton University physicist William Happer was fired from the Department of Energy because he disagreed with Vice President Al Gore's views on stratospheric ozone depletion. In 1994, President Bill Clinton rejected the finding from the Embryo Research Panel of the National Institutes of Health which declared that the intentional creation of human embryos for genetic research was ethical. Clinton simply banned any federal funding for such research.

And in 1993, the EPA used a meta-analysis of a number of studies to find that second-hand smoke caused lung cancer in adult non-smokers and serious respiratory problems in children. That may well be, but the EPA had to put its thumb on the scales in order to get the result it wanted. The agency included just 11 out of 30 known studies on second-hand smoke in its meta-analysis, and even then found no increased risk to non-smokers at the 95 percent confidence level that had been the traditional agency standard. So the agency simply moved the confidence level from 95 percent to 90 percent in order to get the result it wanted.

At the time, I talked to a member of the EPA's scientific advisory board, an epidemiologist working at a leading east coast university who requested anonymity. He told me that he knew it was inadvisable to change the confidence level. He didn't oppose the change, though, because he was afraid he would be kicked off the board if he didn't go along. "I wanted to remain relevant to the policy process", he explained. He was also an EPA grant recipient.' Ronald Bailey, 'Why government isn't the best place to look for unbiased science', reasononline, www.reason.com/news/show/34774.html, (3 March 2004), visited 10 March 2009. And see the NY Times columns and posts to this point

politics is rich with suggestions that the economic importance and political salience of science and technology issues makes them inevitable.[11] As in the case of stem cell research, disputes may often really be about values (eg, the sanctity of human life, understood to begin at conception) rather than science as such, although what one author describes as 'stealth advocacy' may often invoke ostensible science in their support.[12]

Please complete the cross ref.

One may add that a Republican administration encounters a civil service likely to be much less sympathetic to its preferences than a Democratic one.[13] Disregard for the work of the civil service could be seen as an understandable reaction to civil servants' resistance to legitimate political direction.

Still, it is striking that the two administrations prior to that of President Bush, one Republican and one Democratic, found about as many occasions to invoke the Endangered Species Act *each year* as the most recent Bush administration did through its whole term in office[14]—and when the latter did invoke it, that was largely under judicial compulsion. Nor had any prior presidency been so marked by the repeated, anguished phenomena of lifetime government scientists resigning jobs that they had not been permitted to serve in integrity, with repeated accounts of muffled reports of scientific views and findings.

President Obama made the issue of 'restoring scientific integrity' prominent in his successful political campaign, and an applauded theme of his inaugural address. On 9 March 2009, he issued a memorandum for the heads of executive departments and agencies purporting to address these issues. It appears in full in Appendix A to this chapter. It assigns to the Director of the Office of Science and Technology Policy, the White House office responsible for coordinating science matters in government, the task of developing recommendations that will produce merit-based (ie, not political) appointments, use of scientific methods (including peer review as appropriate) in developing information, heightened transparency, and improved protection for dissidents ('whistleblowers'). And scepticism whether this was a change in the service of science or of politics immediately followed.[15] What are the tools law can bring to improve the chance

by John Tierney in the New York Times, eg 'Politicizing Science', www.tierneylab.blogs.nytimes.com/2009/02/27/politicizing-science, visited 10 March 2009.

[11] R Pielke, Jr, *The Honest Broker—Making Sense of Science in Policy and Politics* (Cambridge, Cambridge University Press, 2007); DS Greenberg, *Science, Money and Politics* (Chicago, University of Chicago Press, 2001); S Jasanoff, *The Fifth Branch—Science Advisers as Policymakers* (Cambridge MA, Harvard University Press, 1990).

[12] Pielke, n 11 above.

[13] See n [redacted]elow.

[14] See Sh[redacted]an, n 9 above, at xii–xiii.

[15] S Stolberg, 'Obama Puts His Own Spin on Mix of Science with Politics', NY Times, 9 March 2009; J Tierney, 'Politics-Free Science?', www.tierneylab.blogs.nytimes.com/2009/03/09/politics-free-science, visited 10 March 2009. A later report was that:

> OSTP Director John Holdren met the 9 July deadline in the presidential memorandum for suggesting how executive agencies should improve their conduct on everything from vetting job

that sound judgement, 'reason', will prevail, and to diminish the influence of simple will, 'unreason'?

In asking this question, one must be aware of an important lacuna in the characterisation of science earlier quoted. If 'the scientific process is not democratic', it also will rarely be conclusive in those matters of greatest interest to regulators and politicians. No society committed to democracy can afford to ignore the frequently remarked variations between expert and public evaluations of risk. The observable differences in public willingness to accept risks of varying sorts, even when openly and reliably defined, will produce policy outcomes varying from those that straightforward comparison of objective risk levels would suggest. Motorcycle riders will notice no cognitive dissonance as they campaign vigorously against nuclear power. These are issues that might be addressed by education; but while certainly susceptible of political manipulation, they reflect preferences that cannot be discredited. One might distinguish here between political judgements that develop from democratic discussion processes, and political outcomes that are more directly the product of the exercise of simple, and usually covert, will. It is the latter that are the principal concern of this chapter.

SOME EXAMPLES OF WILL OVER JUDGEMENT

This section sketches four examples of settings in which it might be thought 'will' had prevailed over 'judgement', two drawn from American experience and two from abroad.

Treatment regimes for Lyme Disease

The quotation earlier set out was taken from an article in the Journal of the American Medical Association (JAMA) criticising a decision of the Attorney-General of Connecticut to prosecute the Infectious Diseases Society of America (IDSA) for state antitrust violations. In 2006, the IDSA issued updated clinical practice guidelines in 2006 for the diagnosis and treatment of Lyme disease, recommending against the use of longterm antibiotics to treat 'chronic Lyme disease (CLD)'. The IDSA is a private non-governmental organisation (NGO) that formulates recommendations about disease treatment regimens on the basis

applicants to protecting whistleblowers. But the details remain under seal until all relevant agencies have signed off on them.

www.blogs.sciencemag.org/scienceinsider/2009/09/lost-in-space-t.html, dated 1 September 2009 and visited 20 September 2009. In the interim his Office of Science and Technology Policy had conducted and reported numerous innovative programmes in e-government. See generally www.whitehouse.gov/open/, www.whitehouse.gov/open/blog/, and, in particular, www.mixedink.com/OpenGov/, where a government consultation on improving e-government was recently held.

of available studies. These recommendations are influential on physicians prescribing courses of treatment, and on insurance companies making determinations about coverage. CLD is a label that some use to describe a variety of non-specific symptoms persisting in some Lyme disease sufferers after evidence of bacterial infection has disappeared and for which, frequently, no evidence suggests the etiologic agent of Lyme disease is responsible. IDSA's study, for the authors of the JAMA article demonstrably the product of sound science, had led it to conclude that long-term treatment of these symptoms with antibiotics was ineffective, expensive, and posed the risks associated with long-term antibiotic use. For the International Lyme and Associated Diseases Society (ILADS), however, a CLD advocacy group supported by the manufacturer of the drug used for long-term treatment, and drawing on the work of a committee that included the president of a company that manufactures an alternative Lyme disease diagnostic test and multiple physicians whose practices are listed with the group's patient referral service, these results were anathema. ILADS immediately protested, asserting the superiority of its alternative guidelines; the JAMA article asserts that these guidelines were based on substandard review methods. Within days, the Connecticut Attorney-General launched an investigation, alleging IDSA had violated state antitrust law by excluding differing viewpoints from its guideline creation process and including members who had financial interests in, or ties to, Lyme disease diagnostic and treatment makers. IDSA had disclosed its panel members' potential conflicts of interest in its published guidelines, and the authors of the JAMA article assert that there was no evidence that any conflicts altered the guidelines' content. The committee that created the ILADS guidelines did not disclose the financial interests associated with its guideline document. To avoid exorbitant litigation costs, IDSA was forced to settle the claim and alter its guidelines.

Herceptin and Breast Cancer Treatment in New Zealand

Public subsidisation of medical treatment regimes in New Zealand depends importantly on the judgements reached by Pharmac, a governmental agency whose decisions are grounded in considerations of cost as well as effectiveness. Herceptin is a pharmaceutical that can be effective in treating certain forms of breast cancer, but which itself poses certain health risks if used for a long time, and is quite expensive; a full year's treatment might cost in the range of NZ $70,000 (depending on the patient's weight). From 2001, Pharmac had listed Herceptin as approved for extended use in the treatment of *metastatic* breast cancers. Subsequently, the question arose whether it should also be approved for treatment of women whose breast cancer had been detected at an earlier stage. In 2006, responding to advice from expert committees that called the drug's cost-effectiveness for these women into question, Pharmac decided not to schedule the drug for that use 'at this time'. To approve the use would have had

implications for New Zealand's capacity to subsidise other treatment regimes for the full range of diseases. In 2007, responding to broad consultations and to a study suggesting that a nine-week course of treatment with the drug concurrent with chemotherapy showed a level of effectiveness comparable to that which might arise from a full year's treatment, it decided to list the nine-week course of treatment as approved for subsidisation, but did not reopen the one-year question. In April 2008, responding to review sought by breast cancer sufferers wishing the full year option, quite possibly with support from the drug's manufacturer, New Zealand's High Court found that Pharmac had failed to engage in the required level of consultation in reaching its first decision and, while approving the process attending the second decision, concluded that that process had not reopened the one-year question. It directed reconsideration of that question, after full consultation. Pharmac complied, and came to the same conclusion: the benefit of the one-year regimen was too uncertain in relation to its cost. Within the breast cancer community and to the drug's manufacturer, this was of course a highly disappointing outcome, although others understood it as preventing diversion of necessarily limited public funds from other, more promising uses to support health care generally. The matter became an issue in the national elections later that year, and one party promised as part of its campaign to assure full funding. It won, and promptly acted through the Ministry of Health—not Pharmac—to subsidise the full-year regimen.

A Wind Farm in Australia

The Australian Minister for Environment, a member of the Australian Senate, was required to approve the siting of a large wind-farm at Bald Hills, in southern Australia.[16] The siting was locally controversial for reasons grounded in aesthetics and concern over the noise it might produce. And an election was pending, in which a candidate of the minister's party (the minister was himself from a distant riding) had allied himself with the opposition to the farm. The minister refused to approve the application, citing the risk it posed to a critically endangered species of parrot. The parrot was indeed endangered, and wind farms pose unquestionable dangers to migratory birds. But, as has not been unknown in the United States,[17] ostensible concern for the parrot was a stalking horse for local residents unhappy about a projected intrusion on their amenities. When the reports and data on which the minister had relied became available, it proved that few, if any, of the endangered species had ever been seen in the vicinity of the projected wind farm; their population density, to the extent there was any, lay elsewhere, and the major threat to their survival was development and its

[16] This paragraph is based on J Prest, 'The Bald Hills wind farm debacle' in T Bonyhady and P Christoff, (eds), *Climate Law in Australia* (Sydney, Federation Press, 2007).

[17] *Scenic Hudson Preservation Conference v Federal Power Commission*, 354 F2d 608 (2d Cir 1965).

associated habitat changes. The data suggested that perhaps one parrot would fall to the wind farm every millennium; extinction from other causes was thought likely within 50 years. The availability of this data—and the passage of election day—resulted eventually in a settlement that permitted the wind farm's construction.

Setting the Secondary Level for Ozone in the United States

In the spring of 2008, the public became aware of disagreements between the Bush White House and the Environmental Protection Administration (EPA) about the level of ozone exposure appropriate for national ambient air quality standards to protect forest growth and other 'secondary' targets of protection from harm by air pollution.[18] ('Primary' standards are set for public health concerns.) Reflecting the differences they understood between the needs and vulnerabilities of human and forest lungs, the various scientific advisory committees and bureaucratic decision-makers within the EPA had settled on an ozone level marginally differing from the primary standard. It would have been somewhat more stringent than the primary level but also with a more forgiving measurement interval.

These standards are to be set following the public procedures of the Clean Air Act for rule-making, procedures building on but somewhat more stringent than those of the US Administrative Procedure Act. (In many European countries, the development of similar measures would be described as subsidiary legislation or perhaps ministerial decrees; in the EU, as implementing measures.) Under these procedures as currently understood, the public receives notice of a proposed rule and access to the data and reports underlying it, and any person interested to do so is able to submit additional data and to comment on the proposal; the agency must then explain its decision in some detail and, as already indicated, its reasoning is subject to relatively close scrutiny on judicial review.

The EPA's Administrator, a politically responsible official comparable in dignity to a Cabinet Secretary and who by statute is given the authority to decide such matters, was prepared to accept and act on the advice he had received from his staff. Before he could do so, however, contemporary arrangements (established by the President for White House coordination and oversight of regulatory activity) required him to seek clearance from an office in the President's Office of Management and Budget, the Office of Information and Regulatory Affairs (OIRA). OIRA initially sought reconsideration of the matter, suggesting that the primary and secondary standards would most efficiently be identical—set at the somewhat more permissive level already determined for the primary standard. EPA staff generated a response detailing why, in their judgement, the best

[18] J Eilperin, 'Ozone Rules Weakened at Bush's Behest; EPA Scrambles To Justify Action', The Washington Post, 14 March 2008, at A1.

scientific evidence available about the differing vulnerabilities of humans and forests required differing standards under their statutory responsibilities. The EPA Administrator indicated to the White House, then, that he intended to stand by his staff's judgement. At this point he was directed—told President Bush had decided—that identical standards must be adopted. The Administrator acquiesced.

The resulting blizzard of newspaper stories and congressional inquiries suggested that something untoward had occurred. The relevant statute, placing the responsibility for this decision in the Administrator and not the President, both assumed and required that the decision would be made in accordance with the best available scientific information. Neither the President nor his agent OIRA has the resources or expertise to do good science on such an issue. Moreover, the relevant statute precludes using economic cost/benefit, as such, as a decisional consideration. (While this proposition might seem questionable as a policy matter, it had underlain the US Supreme Court's willingness just a few years earlier to accept the significant law-making authority the statute confers on the EPA's Administrator.[19] Permitting the EPA to make political trade-offs rather than base its actions on ostensibly objective judgements about best science would heighten concerns about the constitutionality of conferring this law-making authority on unelected officials.[20] Suspicions were rife that the White House judgement about ozone was animated by raw political concerns for the well-being of favoured industries; or if not that, certainly by the factors of economic cost that the statutes had excluded from the Administrator's consideration. Congressional committees demanded, and the White House adamantly refused to provide, a variety of documentary evidence and testimony on the issue. The standard was issued in the form the White House had insisted upon, and in that form might be subject to judicial review.[21]

[19] *Whitman v American Trucking Ass'ns, Inc* 531 US 457, 475 (2001) ('While Congress need not provide any direction to the EPA regarding the manner in which it is to define "country grain elevators", which are to be exempt from [certain statutory requirements], it must provide substantial guidance on setting air standards that affect the entire national economy').

[20] *cf Boreali v Axelrod* 71 NY 2d 1 (1987) (New York's Public Health Council authorised to consider only public health factors in adopting a regulation controlling smoking in public places; it lacks the 'open-ended discretion' to construct 'a regulatory scheme laden with exceptions based solely upon economic and social concerns').

[21] On 16 September 2009, the EPA Administrator announced that she was reopening the standard, which presumably will moot any review petition that may have been filed. www.yosemite.epa.gov/opa/admpress.nsf/6424ac1caa800aab85257359003f5337/85f90b7711acb0c88525763300617d0d!OpenDocument, visited 20 September 2009.

In a similar Bush administration episode, OIRA delayed for years action on a proposed regulation to protect an endangered species, right whales, from collisions with large boats traveling at speeds that made evasion difficult; the regulation was eventually issued in the form the responsible agency had requested but only after more than a year later than the action times assured by the order creating the OIRA review regime. See Robbie Brown, 'US Requires Ships to Cut Speed in Waters Used by Right Whales', NY Times, 9 October 2008.

That the back-and-forth became public is due in substantial part to the increasing availability of information about governmental regulatory activities on the Internet. The EPA has been one of the leading agencies in developing public Internet databases associated with its rule-making activities. As a matter of the [redacted] text, the obligations to expose matters concerned with rule-making appear to be rather slight. Nonetheless, judicial decisions and the realities of the US Freedom of Information Act have resulted in thorough agency exposure of the scientific reports or data on which rule-making decisions may be based, as well as commentary received from outside the agency. The idea that this should happen is uncontroversial, and is strongly voiced in President Obama's recent executive order. To the extent such information is made available and searchable on the Internet, as increasingly it is, citizen monitoring is facilitated. And, responding in part to commitments made in the OIRA mandate, the computerised database for the ozone rule-making quickly included much material revealing the back-and-forth that had occurred. Perhaps a knowledgeable EPA official then suggested to the reporter that he have a look.

THE ROLE OF RULE-MAKING

Each of these examples could be thought to raise the question how the timeliness and internal integrity of government regulatory decision-making can best be promoted. Choices to prosecute (Connecticut), to allocate public funding (New Zealand), to approve an application (Australia) or to adopt a standard (EPA) can all be influenced by factors other than a reasoned judgement about 'best science'. Yet to recognise that this is so, in a democratic society, is not necessarily to condemn that outcome. In the New Zealand case, for example, one might well think that although a large corporation's profit motivations may have influenced the outcome, the spending choice between marginally beneficial breast cancer treatment regimes and other purposes was also a matter that had been contested in the citizenry and was proper for political determination. In this case that decision was openly made in a straightforwardly political way. In the other three cases, one could believe that timely public information about the objective realities underlying the decision could have produced different results. The issues are ones both of procedures employed, and of the place of politics in the determinations made.

The focus of inquiry in the paragraphs following will be on rule-making—the generation of regulations that if valid have the force and effect of statutes—rather than adjudication. Policy issues of broad interest more frequently arise in that context, and there are interesting parallels between the ostensible public procedures for rule-making, as they have developed in the United States, and the paradigmatic methods scientists use to inform their judgements. The 'paper

hearing' of today's important rule-makings—marked by detailed notice including the availability of underlying data; a seriously taken opportunity for comment; an extensive explanation of agency reasoning in the face of that comment; followed by 'hard look' judicial review—seems remarkably like the scientific method for approaching truths.

The matrix for these paragraphs will be that suggested by President Obama's recent directive on restoring scientific integrity,[22] which focuses in turn on selection and retention of candidates; internal procedures including 'well-established scientific processes' such as peer review; and issues of arising out of central government control of rule-making, including transparency, protection for dissidents, and White House relations.

Supply cross ref

Selection and retention of candidates

The executive order directs that selection of candidates 'should be based on the candidate's knowledge, credentials, experience, and integrity.' Left off this list of desirable qualities are such typical criteria for political appointment as loyalty and a known predisposition to agree with the President/agency head's policy preferences. One might find room for these qualities in the interstices of 'credentials, experience, and integrity', the language President Obama used in his recent directive; and appraisals of President Obama's own appointments to scientific posts have not been lacking in suggestions that they have been used.[23] Nor can one imagine that persons possessing 'credentials, experience, and integrity' lack political commitments, or predispositions on issues in play in the scientific community respecting which final judgement has yet to be reached. In his short recent book, *The Honest Broker*, Roger Pielke, Jnr valuably distinguishes between the kinds of political issues that can be appropriately resolved by reliable inquiry into observable facts—is a tornado approaching? 'tornado politics'—and others that cannot, 'abortion politics'.[24] To the extent reliable inquiry cannot produce uncontested answers—very often the case in situations where politicians nonetheless feel required to act (say, respecting climate change)—the engaged scientist is faced with the choice between acting as 'stealth advocate', proceeding on the basis of his or her personal belief or preference, and acting as 'honest broker', stating clearly the alternatives and their associated uncertainties and implications while subduing as best he or she can his or her own priors.

[22] Text at n [redacted] bove.

[23] eg, J Tierney, "Findings: Politics in the Guise of Pure Science," NY Times, 24 February 2009, at D1.

[24] Pielke, n 11 above, at 40.

Committing scientific data-gathering to the civil service?

In speaking to the 'selection of candidates', President Obama is of course addressing the appointees he and his political lieutenants choose and not the members of the permanent civil service. One mechanism that might be thought useful to encourage 'honest broker' behaviour is a definition of function to separate, so far as possible, the responsibility for appraising those issues for which scientific inquiry may be helpful, such as risk, from questions on what to do about such matters once identified. Such a separation could map onto the ostensible distinction in government employment between the permanent civil service, and political appointees who hold office at will and ordinarily change with administrations.

A distinction between risk managers and risk assessors is explicit, for example, in the standard setting activities of the Codex Alimentarius Commission under the aegis of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). This body undertakes setting international standards for food safety to ensure human health protection, in light of the best available scientific data.[25] Its documents conceive overall risk analysis as comprised of three functionally separated elements: risk assessment, risk management, and risk communication. The allocation is in the service of creating a zone in which 'scientific integrity' may be assured (risk assessment); another in which political judgements are made and from which guidance and standards emerge (risk management); and a third element of systematic, maximally sustainable transparency that may build public trust (risk communication). Risk assessors are encouraged to identify the data, assumptions and uncertainties bearing on their assessments, and the characteristics of the hazards they identify, and to report their conclusions in a manner permitting peer and public review. Risk managers, taking a range of economic and political factors into account, are to respect 'precaution' and public attitudes towards risk in deciding how best to respond to the assessments thus received; again, their processes and reports should be 'transparent, consistent and fully documented'. Both assessors and managers, while respecting 'legitimate concern to preserve confidentiality', are encouraged to communicate their activities and conclusions with the greatest accuracy and transparency possible, so as to strengthen working relationships and build public trust.

Distinguishing between risk assessors (scientists) and risk managers (the policy-setting overseers to whom they report) might be thought naturally to fit the presuppositions of a permanent civil service working within a framework of political management. That is, one might think, the data gatherers, the risk assessors, are unlikely to have political ambitions or roles; that is the whole point. If initially the impulse to creation of a civil service imagined a body of secretaries

[25] Its Working Principles for Risk Analysis for Food Safety for Application by Governments, CAC/GL 62–2007, is attached as Appendix B to this chapter.

and clerks, and was intended to control the financial and general competence risks of patronage, one may now see it as a means of assuring the best information for government managers—as an instrument for integrity in a different sense. Selection will be made on the basis of objective criteria. Of course some managers are also scientists, the ones whose appointment President Obama was addressing; the relationship between managers and responsible staff in general, ripe with potential for misuse, is addressed below.[26]

Supply cross ref.

This intellectual separation is intuitively appealing, and certainly sends useful signals to those minded to heed them. It could be seen to reinforce the 'honest broker' vision of scientist function. But as appears amply in the literature, the uncertainties of outcomes and predispositions of analysts confound its reliability.[27] 'Stealth advocacy' can readily appear at the level of risk assessment, whether or not risk management is identified as a separate task. The scientist who has chosen a civil service career has often sacrificed financially more rewarding avenues, perhaps for competitive reasons suggesting his or her possession of a lesser skill set yet perhaps, instead, in order to serve normative preferences that make public service seem worth that sacrifice. One readily understands the political managers' fearing this influence, particularly politicians whose attitude toward the project of government is more sceptical than those who choose a lifetime career in it.[28] To them, at least, 'stealth advocacy' in the memos they receive will appear a significant threat.[29]

It is unlikely, moreover, that an agency's civil servants will themselves be able to amass and analyse the data required for risk assessment. Often they will be required to call upon outsiders more expert than themselves, perhaps as 'special government employees' or perhaps by requesting or contracting for relevant studies. Now their neutrality may not suffice to satisfy; the Lyme disease example from Connecticut underscores the importance of considering what controls exist over the potential conflicts of interest among outsiders relied on for help in assembling/assessing relevant data. If we are evoking 'science' as a rationale, moreover, that entails the values of transparency and openness to refutation. 'Whether a scientific finding is judged to be accurate is dependent on the quality and rigor of the methods used and whether that finding is replicable.'[30]

Supply cross ref.

[26] See pp 0 [illegible] w.

[27] eg, Jasanoff, *The Fifth Branch*, n 11 above.

[28] 'A bureaucrat is a Democrat who holds some office that a Republican wants.' (Alban Barkley, Harry Truman's Vice President, at the 1948 Democratic Convention, as reported in William Safire, *Safire's Political Dictionary* (Oxford, Oxford University Press, rev ed 2008) at 90; the quotation is sometimes attributed to President Truman himself, as at www.members.tripod.com/aldems/page20.html, visited 27 April 2009.

[29] See AF Wichelman, 'Administrative Agency Implementation of the National Environmental Policy Act of 1969: A Conceptual Framework for Explaining Differential Response' (1976) 16 *Natural Resources Journal* 263, on the motivation of government bureaucrats; also discussed in S Taylor, *Making Bureaucracies Think* (Stanford University Press, 1984) and M Painter, *Steering the Modern State* (Sydney, Sydney University Press, 1987).

[30] Note [illegible] bove.

For reasons such as these, 'risk assessment' may be seen as an appropriately public procedure, one that ought to be as contestable and open as the debates over risk management that will follow it. Now the separation virtually disappears. 'Bending'—that is to say political rather than science-process reasons for decision—may have much to do with the arguments about procedure. Much of the (frequently industrial) pressure to formalise 'risk assessment' as an initial, distinct step preparatory to 'risk management' can be understood as an instrument of delay. The EPA should not be required to coordinate with the Department of Defense in assessing the 'toxicity of perchlorate, a component of rocket fuel detected nationally in drinking water, breast milk, and produce', one activist, consumerist science NGO has argued, as this 'could mean that the DOD and its contractors are liable for potentially billions of dollars in cleanup costs. The DOD has long sought to weaken any scientific standard that would mandate cleanup of perchlorate contamination.'[31]

Even at what may appear to be the apolitical, civil service level, as a recent fine analysis by Professor David Barron of Harvard, a former Deputy Solicitor-General in the US Department of Justice, points out, one of the significant threats to scientific integrity is the much enlarged penetration of 'political clearances' into agency bureaucracies. Like OIRA's regulatory review mechanisms, this trend became pronounced with the administration of Ronald Reagan. Barron reports that:

> the number of full-time political appointees serving in the federal government [in policy positions] jumped from 2150 in 1964 to 3687 in 1992. …These [positions, with 2300 others effectively open to political clearance] … dwarf, by orders of magnitude, the number of political appointees available to the executive leaders of most European nations. … The rise in the ranks of economists, engineers, scientists, and lawyers within the bureaucracy itself increases the opportunities for Presidents to remake the bureaucracy in ways that are likely to promote a particular view of regulatory policy.[32]

The increasing scope of political clearance for persons having policy responsibilities certainly renders American 'administration' more political than might be expected in the strong civil service regimes of many parliamentary democracies. Probably the move in this direction began during the presidency of Jimmy Carter, when a reform of the civil service laws created in the upper echelons of the civil service a Senior Executive Service, those persons responsible for policy direction and other matters involving substantial discretion. In the United States as in European democracies, important federal bureaus, elements perhaps of a

[31] 'Scientific Integrity', a submission of the Union of Concerned Scientists to the public comment files respecting revision of EO 12866, see note and accompanying text below, www.reginfo.gov/public/jsp/EO/fedRegReview/publicComments.jsp (visited 12 March 2009), citing Sass J 2004. US Department of Defense and White House working together to avoid cleanup and liability for perchlorate pollution in *International Journal of Occupational and Environmental Health* (abstract) 10:330–34.

[32] DJ Barron, 'From Takeover to Merger: Reforming Administrative Law in an Age of Agency Politicization' (2008) 76 *George Washington Law Review* 1095, 1123.

cabinet department, might be under the direction of a senior civil servant, a permanent government employee rather than a political appointee.[33] Perhaps, one would think, smaller numbers of politicians at the top, and a civil service enured to 'Yes, Minister' in parliamentary systems make for a rather different picture. It should not be hard to understand the stress such penetration can put on the interface between law and politics.

Scientific integrity at the management level

Turning to the context of risk management: the White House and the political heads of agencies do have significant control over agency management levels. At least three strata of management-level employee can be identified. At the highest level are heads of departments and others whose appointment requires Senate confirmation. Here one can find not only public processes for exploring the merits of appointment, but also the possibility of undertakings to others than the President—that is, to the Senators who confirm—that provide a kind of cover for independent judgement. Second come a much larger number of persons appointed by the President alone, or by the heads of departments, without need for Senate confirmation. Like those whose appointment do require that step, they generally[34] serve 'at will' but now without either the cover of undertakings to the Senate, or the same basis for belief that their summary dismissal might produce the kinds of political controversy that could make a President hesitate to act. Strikingly, 100 days into the Obama administration the Library of Congress was reporting 177 nominations submitted to Congress for civilian positions,[35] but as Professor Barron's analysis shows, thousands more politically cleared positions exist outside congressional control. Third and finally, there is the Senior Executive Service—lifetime civil servants in senior positions who, since President Carter's administration, have served in a regime considerably more exposed to reward and punishment for desired and undesired actions than the ordinary civil service. Bureau chiefs may in the past have had the independence of full civil service status and consequent effective room within which to manoeuvre;[36] their service today is much more subject to political controls.

Persons living in parliamentary systems built over permanent civil service bodies find the resulting level of politicality in American government astounding. Mutual understandings about the security of lifetime governmental employment are understood to be a major assurance of the integrity of technical assessments.

[33] The classic study of their work, written at about the time of this change, is H Kaufman, *The Administrative Behaviour of Federal Bureau Chiefs* (Washington, The Brookings Institute, 1981).

[34] The reservation is made to recognise that Congress has occasionally limited dismissals of persons appointed with and without senatorial confirmation to 'good cause'. Thankfully, the Supreme Court has not yet had an occasion to address what might constitute 'cause' in a legal sense.

[35] www.thomas.loc.gov/home/nomis.html, visited 20 September 2009. The number had become 300 by mid-June, 477 by 20 September. By the last date, 328 of the nominations had been confirmed.

[36] Kaufman, n 33 above.

While the creation of inspectors general (serving in this respect a function similar to ombudsmen in European administrations) and whistleblower protections such as President Obama recently re-emphasised provide some protection for scientific integrity, their cover is not complete. Thirty-two years ago, when the author was General Counsel of the US Nuclear Regulatory Commission, its Bureau 'executives' sometimes exercised rigorous control over what they would permit their staff members to tell the Commission about perceived nuclear power risks.[37] Nor were Commissioners wholly committed to transparency about possible risks; facing the chance that utilities or equipment manufacturers might bring similar pressures to bear on their personnel to suppress safety concerns they might wish to share with the Commission and aware that their statute affirmatively provided for whistleblower protection, they did not seem eager to encourage 'rat finks'. Such phenomena suggest what must be obvious, that personal integrity and a willingness to subdue personal preferences are irreducible elements of the 'bending' problem.

To the extent the White House controls the selection of agency personnel, the risk that judgements committed to the agency for decision will be made on bases other than those its constitutive statutes commit to it increases. Professor Barron has amply illustrated these risks in his recent article.[38] They are perhaps magnified by a quixotic Supreme Court decision taking the position that anyone holding an executive branch office with significant authority to act constitutionally, yet not senatorially confirmed, *must* be appointed by either the President or the head of a cabinet department, narrowly understood.[39] And the intensity of senatorial inquiry for those appointments that require confirmation may have at least two consequences promoting White House control. First, by encumbering that process—helping to explain the observable slowness of both nomination (as potential candidates are vetted to avoid embarrassments) and confirmation—it produces enduring *agency* vacancies in ostensible political positions,[40] inviting direct White House engagement in the interim. Second, the same costs rationally lead the President to prefer locating responsibility, to the extent he can, in persons he can place quickly in a position to act, and who are not required to answer Senate inquiry, perhaps creating a conflicting sense of political obligation. It is easy to understand the increasing use of White House 'czars' in this light.

While in parliamentary systems it may be natural for the prime minister to see himself as a persuader/conciliator open to constructive dialogue and shared

[37] Not without chastening consequence; one suppressed employee went to the CBS programme, 'Sixty Minutes' with his concerns, producing both public scandal and congressional hearings that consumed a great deal of the time the Commissioners might otherwise have had for regulatory matters.

[38] N 32 above.

[39] *Freytag v Commissioner*, 501 US 868 (1991).

[40] Seven months into the Obama Administration, just 43% of more than 500 positions requiring Senate confirmation had been filled. See P Baker, 'Obama Team Lacking Most of Top Players', NY Times, 24 August 2009, at A1.

responsibility, the 'unitary executive' idea, pursued to its theoretical limits, has other implications. In recent writings, Robert Post has pointed to the differences from the perspective of democracy between political conceptions that are centered on loyalty—you are with me or you are my enemy—and others that welcome disagreement, preferring a team of rivals from which judgements can emerge by a process of constructive conversation.[41] In the Bush administration, it often appeared that the first duties of civilian heads of departments, like generals of the Army, were thought to be loyalty and obedience—a perspective that may conduce to efficiency in executive governance but offers less promise to democracy. For President Harry S Truman, who regarded the President's office as one of conciliation and persuasion, 'Whenever you have an efficient government you have a dictatorship.'[42] In the first months of the Obama administration, some disposition to hear all sides—to enlist 'honest brokers'—might be suggested by the President's appointment of his principal political opponent to be his Secretary of State, and his reputation as a person committed to hearing all sides. His nomination of a former colleague, Professor Cass Sunstein, to head the office most directly concerned with domestic regulation, the Office of Information and Regulatory Analysis (OIRA) in the Office of Management and Budget (OMB), would put in that important post an academic whose recent writings have repeatedly stressed the importance of hearing all sides for sound decision.[43] Yet an 'Inside Account' of the President Bush's controversial decision on stem cell research persuasively portrays it, too, as the product of intense internal dialogue;[44] and President Obama's undertakings of increased transparency, unsurprisingly, have yet to result in significant public exposure of advice he has received from within the executive branch.[45] Truman again:

Supply cross ref.

> President cannot function without advisers or without advice, written or oral. But just as soon as he is required to show what kind of advice he has had, who said what to him, or what kind of records he has, the advice received will be worthless.[46]

[41] See, eg, R Post, 'Theorizing Disagreement: Re-Conceiving the Relationship between Law and Politics' *California Law Review* (forthcoming), *Yale Law School Public Law & Legal Theory Research Paper No. 195*, available at www.papers.ssrn.com/abstract #1434103.

[42] Harry S Truman, *Lecture at Columbia University, 28 April 1959*, www.quotationspage.com/quote/27058.html, visited 21 April 2009.

[43] See CR Sunstein, 'The Empiricist Strikes Back', *The New Republic*, 10 September 2008, at 9; T Kuran and CR Sunstein, 'Availability Cascades and Risk Regulation' (1999) 51 *Stanford Law Review* 683.

[44] J Lefkowitz, 'Stem Cells and the President—An Inside Account', Commentary (January 2008), www.commentarymagazine.com/viewarticle.cfm/stem-cells-and-the-president-br–an-inside-account-11024?page=all (visited 3 June 2009).

[45] Prominent among a number of public consultations begun by the Obama administration within its first 100 days in office was one in connection with its reexamination of Executive Order 12286, discussed further below. See text below accompanying n

[46] H Truman, *Memoirs: Years of Trial and Hope* (New York, Garden City,1956).

Supply cross ref.

Further discussion of the transparency side of these issues will be found below, as well as an examination of the White House control mechanisms.[47] But in concluding a discussion of the appointments issues, as such, some mention is warranted of the resistance of recent Presidents to congressional instructions about appointment qualifications; these Presidents have asserted an essentially constitutional right to propose whomever they wanted. President Clinton appended such a statement on signing a bill that, inter alia, sought to limit the pool of persons he might nominate for US Trade Representative to avoid arguable conflicts of interest. In the wake of the Katrina disaster and the deficiencies in Federal Emergency Management Administration (FEMA) management it revealed, Congress passed statutes requiring that the person appointed to head FEMA be a person experienced in the management of complex institutions and disaster management.[48] In a later statute, it directed that appointees to high office in the United States Postal Commission have similar experience-related backgrounds.[49] In signing the lengthy statutes including these provisions into law, President George W Bush identified these two provisions in particular, as against many he accepted, as unconstitutional infringements of his authority to nominate or appoint anyone he chose.[50] The obverse of congressional creation of appointments limits suggesting commitments to, for example, professional integrity is that openness to political direction in the face of those commitments can be highly valued.

One area of personnel control that has long been thought important, in science as in politics, is the subduing of personal financial advantage—not power, now, so much as greed. Both formal conflict of interest requirements and attention to the loyalties likely to persevere from prior activities and commitments operate here. The presuppositions of a civil service that invites transition between public and private life, as the American one does, at both leadership and staff levels, creates inevitable tensions. These are dealt with, but imperfectly, by financial controls and by restrictions on 'revolving door' service. One President appoints a construction executive to head the Occupational Safety and Health Administration; another, an industrial safety professional with union connections. Each on leaving office may return to a post similar to that from which he or she came; either may be preferable to appointing a skilled administrator who is inexperienced about issues of workplace safety; both may return to

[47] See pp

[48] Department of Homeland Security Appropriations Act 2007 § 611(11), 6 USC § 313.

[49] Postal Accountability and Enhancement Act 2006 § 501, 39 USC § 202.

[50] Statement by President George W Bush Upon Signing HR 5441, 2006 USCCAN S49, S52 (4 October 2006) ('[the statute] purports to limit the qualifications of the pool of persons from whom the President may select the appointee in a manner that rules out a large portion of those persons best qualified by experience and knowledge to fill the office. The executive branch shall construe [section 611] in a manner consistent with the Appointments Clause of the Constitution.'); Statement by President George W Bush Upon Signing HR 6407, 2006 USCCAN S76 (20 December 2006) (making an almost identical statement).

private life with increased skills and understanding that in fact serve to aid their clients' attention to industrial safety realities. And for both, questions can be raised about the 'objectivity' of their attention to programmatic issues.

Conflict of interest regulation and revolving-door control have been recurrent issues in the United States. President Obama made strong commitments to avoiding appointments questionable on such grounds, yet some of his initial designees withdrew in embarrassment after compromising connections or lapses came to light. Others did not and, as with Secretary of the Treasury Geithner, it is not surprising that appointees bring with them prior commitments or experience that seem likely to influence their judgement. Attention to such issues is perhaps easier, and more readily regularised, at lower levels—as, for example, assurance of balance and lack of conflict in the advisory panels that work with the Food and Drug Administration or the EPA.[51] The literature is replete with examples of settings in which these efforts have not been successful and, indeed, it may be hard even in the academy to find a pharmacological expert who has not had financial dealings with the drug industry. The FAO-WHO Codex Alimentarius process already mentioned commits to having experts involved in risk assessment publicly known, transparently selected, and free of potentially disabling conflicts of interest. The FAO questionnaire on the subject explores in considerable detail, for individuals and also their families and business connections, a wide range of financial and other interests that could raise such questions—seeking explanations where potential conflicts arise, presuming consent to disclosure of the document, and suggesting that disqualification may occur if disclosure is refused.[52] But with disclosure, appointments are not disqualified.

Procedures

Incentives for integrity might also be found in objectivised, procedural controls over rule-making. We can briefly mention two—judicial review of the outcomes, and peer review of the relevant science. In doing so, however, one must bear in mind the caution suggested by the noted American scholar Jerry Mashaw, writing about procedural choices in the context of administrative adjudications affecting individual rights. Mashaw persuasively argued the point that there is no 'best' answer. He identified three perspectives from which this question could be approached: individual fairness, affording maximum attention to the process claims of the individuals whose rights are at stake; professional integrity, considering *both* the arguable contributions made to sound decisions by the professional commitments of the deciders *and* the possible interference with these

[51] See, eg, McGarity and Wagner, n 4 above, at 181–203.
[52] The questionnaire is attached as Appendix C to this chapter.

contributions that could be created by procedural details;[53] and bureaucratic rationality, which would value the confinement of likely error to cases 'on the borderline' and efficiency—low cost in relation to the issues to be determined.

> If these hypotheses are correct, then it may also follow that the best system of administrative adjudication may be the one most open to criticism. A compromise that seeks to preserve the values and to respond at once to the insights of all of these conceptions of justice will, from the perspective of each separate conception, appear incoherent and unjust. The best system of administrative adjudication that can be devised may fall tragically short of our inconsistent ideals.[54]

And, of course, procedural requirements may not only contribute to more accurate or efficient, or fair outcomes. They may also provide 'handles' that participants eager to add delay or expense to government determinations can use to achieve that. As long-time American Congressman John Dingell is reported once to have observed, 'If you let me write the *procedure*, and I let you write the substance, I'll screw you *every time*.'[55] Many believe that the notorious slowness and infrequency of rule-making on issues of occupational safety and health is the product of industrial success in securing cumbersome and expensive procedural requirements in a law whose purpose of improving worker safety they could not directly oppose. Claims to improving fairness and accuracy were a different matter.

So the same kinds of trade-offs as Mashaw remarked for the setting of adjudication may be implicit in providing procedures for standard-setting. Even if we start with the proposition that the standards to be set should reflect as is best possible the state of scientific knowledge, we can identify significant elements that will influence the timeliness, accuracy and acceptability of the outcomes. Rule-making in American law is a public procedure, with agencies statutorily required to solicit public comment on any proposal before acting on it, and to explain their reasoning in response to comments and other materials when they do act. American case law has largely established propositions central to the language in President Obama's recent executive order providing that:

> (1) … (c) When scientific or technological information is considered in policy decisions, the information should be subject to well-established scientific processes, including peer review where appropriate, and each agency should appropriately and accurately reflect that information in complying with and applying relevant statutory standards;

[53] Examples might be teachers or doctors, whose professional commitments have often been relied upon. In the welfare context, the proceduralisation of welfare administration in the wake of *Goldberg v Kelly*, 397 US 254 (1970), brought about a shift in hiring from social workers, professionally committed to the wellbeing of their clients, to caseworkers with an eye to the bottom line. See WH Simon, 'Legality, Bureaucracy, and Class in the Welfare System' (1983) 92 *Yale Law Journal* 1198.

[54] JL Mashaw, *Bureaucratic Justice: Managing Social Security Disability Claims* (New Haven, Yale University Press, 1983).

[55] M Foley and JE Owens, *Congress and the Presidency: Institutional Politics in a Separated System* (Manchester, Manchester University Press, 1996) (emphases added).

> (d) Except for information that is properly restricted from disclosure under procedures established in accordance with statute, regulation, Executive Order, or Presidential Memorandum, each agency should make available to the public the scientific or technological findings or conclusions considered or relied on in policy decisions.
>
> (e) Each agency should have in place procedures to identify and address instances in which the scientific process or the integrity of scientific and technological information may be compromised …

And as long as three decades ago, a thoughtful writer celebrated the proposition that judicial review of rule-makings, requiring what our courts have called a 'hard look' at matters in controversy, armed those within an agency who cared about reasoned decision-making (ie, acts of judgement) with a weapon with which to influence those who did not (ie, prefer acts of will).[56] The other side of this, however, has been the plaint recurrent in the American literature that the 'hard look' has produced ossification—by making it too costly for agencies to produce regulations, and providing the opponents of warranted regulation with too many tools by which to delay or obstruct it.[57]

Perhaps nowhere in American administrative law have ossification concerns been voiced more loudly than in connection with the issues of peer review and information quality—both issues on which the executive order appears to make commitments. Does peer review add another step to what is already a time-consuming, resource-expensive process? In the realm of 'pure science' (or review for publication in science journals), peer review might be characterised as merely the process that happens (assessments and efforts at replication that conduce to validity), and the passage of time is not so relevant as a factor. Add financial or power consequences to truth-seeking, and social consequences to delay, however, and matters become considerably more complex. If it is to be conducted outside government (that is, using scientists whose connection with public service is no more than as a special employee), can adequate assurances be attained that the reviewing peers will not be interested ones? The Bush administration's efforts to put peer review mechanisms in place were widely criticised for their perceived tendencies to produce delay and to arm regulatory opponents without notably improving regulatory outcomes. A so-called 'Information Quality Act' was inserted by stealth in an omnibus budget statute during the Bush administration, and seen by many to have similar tendencies. 'More study is required' is notoriously an obstacle to action—appropriate at times, but readily wielded in a wider range of circumstances.

One does not too readily find enforceably mandated procedures like the American ones for the adoption of regulatory measures in other political systems. The European Union engages in advanced public consultations about proposed

[56] WF Pedersen, Jr, *Formal Records and Informal Rulemaking* (1975) 85 *Yale LJ* 38, 59–60.

[57] A sceptical note has recently been sounded about these claims by S Shapiro, 'Explaining Ossification: An Examination of the Time to Finish Rulemakings' (11 August 2009). Available at SSRN: www.ssrn.com/abstract=1447337 (Visited 20 September 2009).

legislative actions; for subsidiary legislation corresponding to American rule-making, however, it deploys the somewhat obscure process of comitology, which lacks similar commitments.[58] In the development of Codex Alimentarius standards, FAO-WHO employs a process resembling American notice and comment rule-making, with some exposure of data, opportunities for comment by interested persons, and an ostensible commitment to objective, science-based judgement. Adoption, however, is political, by agreement of the Member States; the extent to which transparency is actually achieved, by documents or through the Internet, appears uncertain (perhaps especially at later stages); and it does not appear there is any objectivised test of the reasoning that may be employed. In parliamentary democracies the responsibility of ministers to the Parliament is often, if not invariably, accepted as a sufficient basis for their exercise of rule-making powers.

Recent, broadly grounded studies by members of the science community have emphasised the positive contributions of embracive participatory processes to the quality as well as the acceptability of judgements made in contexts like these.[59] Building on the dominant ethic of scientific inquiry—the full reporting of approaches, data, reasoning and results, with open acknowledgment of and attempts to frame uncertainties—these studies stress transparency and candour as root values of the iterative processes they imagine. Of course certain realities intrude when translating the conditions of scientific inquiry to the world of government action. Securing the cooperation of commercial participants, often essential, may depend on effective capacity to assure them that information they provide will not be revealed to competitors or in other respects imperil their interests. Government actors will not be disposed or able to await the definitive resolution of all issues in the face of needs for action, not merely knowledge. Not every participant in a process will be motivated simply by the pursuit of accurate understanding. Concerns for efficiency, and for protection against manipulative uses of opportunities afforded for participation, have consequent force.

A further complication is introduced by the fact, frequently remarked, that the public simply does not evaluate risks the same way experts do. New Zealand's experience with Herceptin might be taken as an exemplar of this problem: where administrators deemed the benefits of a full year of treatment too uncertain to justify diverting public funds, yet the public (whose funds they were) voted in favour of the diversion. In a democratic society, such electoral choices and the value judgements they reflect cannot be dismissed.

[58] See generally PL Strauss *et al, Administrative Law of the European Union: Rulemaking* (Chicago, American Bar Association, 2008).

[59] T Dietz and P Stern (eds), *Public Participation in Environmental Assessment and Decision Making* (Washington, National Research Council, 2008); J Chilvers, 'Deliberating Competence: Theoretical and Practitioner Perspectives on Effective Participatory Appraisal Practice' (2008) 33 *Science, Technology & Human Values* 421.

Central government controls and politics

Oversight or Control?

Recent years have seen both a significant expansion of agency control mechanisms in the White House itself and, as mentioned above,[60] much enlarged penetration of 'political clearances' into agency bureaucracies. While the controls centered in OIRA, discussed further below, have attracted the most scholarly and congressional attention, Lisa Bressman and Michael Vandenbergh's groundbreaking account of the EPA-White House interface from the perspective of EPA political appointees dramatically illustrates the number of White House voices (in both Republican and Democratic administrations) purporting to exercise 'presidential control'.[61] President Obama's appointments to White House positions—for example, a former EPA administrator, Carol Browner, to a new position as White House Coordinator of Energy and Climate Policy, 'climate czarina'—suggests that this reality may persevere. The prompt annulment of President Bush's Executive Order 13422, on the other hand, withdrew certain personnel requirements for responsibility *within* agencies that might have been seen as additional political controls.[62]

Supply cross ref.

An entirely separate issue, and the one that initially catalysed this writing, concerns the place of political controls, and perhaps especially centralised executive political controls, over the outcomes of standard setting activities. American arrangements for the allocation of executive authority typically place responsibility for science-based decision-making in civil service-dominated agencies rather than the political White House. When the legislature has empowered a particular organ of government to create regulations—subsidiary norms—to carry forward a statutory scheme that imagines technical or scientific judgements being made, what is the appropriate reach of centralised executive oversight or control?

Consider the ozone regulation episode described above. The bureaucratic structures President Bush employed in interacting with EPA did not originate with him, but have been steadily developed by American presidents at least since the administration of Richard Nixon, most notably by Ronald Reagan and Bill Clinton.[63] Their current expression is in Executive Order 12,866, an order initially created by President Clinton and then somewhat modified by President Bush. The order, in basic outline, creates three stages for agency consultation with the White House during rule-making: first, consultation with the White House

[60] See text accompanying n [illegible]ove.

[61] LS Bressman and MP Vandenbergh, *Inside the Administrative State: A Critical Look at the Practice of Presidential Control* (2006) 105 *Michigan Law Review* 47, 47–52.

[62] Exec Order No 13,422, 72 Fed Reg 2763 (23 January 2007), essentially required every agency to place control over its rule-making operations in the hands, not of the agency head, but of a staffer directly responsible to the White House.

[63] Such a regime was first given formal public shape by President Jimmy Carter (Exec Order 12,044); precursors can be found in the presidencies of Richard Nixon and Gerald Ford.

about their rule-making priorities (the 'regulatory plan', which is published annually in advance of any particular proposals); and then draft and final analyses of particular rules to be proposed and perhaps adopted in carrying out the plan. For the latter stages, the order directs agencies, to the extent consistent with law, to engage in structured analyses of the projected costs and benefits of rule-making proposals, assessing the projected costs and benefits of alternative approaches and choosing that policy which maximises benefits in relation to costs and in other respects conforms to presidential policy preferences. The intensity of this effort and of OIRA's supervision of it is to vary with the importance of the rule; the greatest effort is required for proposals likely to add $100 million or more annually to industrial costs or in other respects have a major economic impact.

Although not statutory, the existence and general shape of this regime have been accepted by Congress, which has passed several statutes assuming its existence and continuation, and by the academic community. Rule-making is understood to be too important to national well-being for there not to be a strong central voice and regime for coordination and settlement of interagency dispute. Through the Clinton administration at least, the disputes that have arisen about it could be characterised as marginal: the nature and extent of its transparency; the precise nature of the inquiry to be conducted; the balance OIRA should strike between supervision of agency processes in general and detailed attention to particular proposals; and the threshold beneath which only superficial OIRA engagement is appropriate.[64]

Probably the most important criticism has been that, as administered, Executive Order 12866 has too often proved not to be a neutral device, but rather a deregulatory device—a source of delay and diversion, a pressure point for reduction of burdens and not actions to protect the public. A narrow focus on monetised 'costs' and 'benefits', in relation only to regulatory actions agencies have in fact proposed (and not, then, to their priority choices), has largely been responsible for that. But beyond this is the possibility that presidential involvement has led to decision based on considerations other than those the agencies explain in their statutorily required 'statement of basis and purpose'.

In the American context, the controversy about the chief executive's engagement with rule-making has a number of elements, some of which are doubtless (and perhaps happily) unique to it and may be seen to illustrate ongoing disputes about the nature and extent of the American President's authority in relation to the decisions of domestic government. Our Constitution vests our President, our one elected executive official, with 'the Executive power', in a largely undefined way. Does that entitle him to *decide* every matter the Congress may delegate to

[64] OIRA will doubtless remain a small office, and one lacking the expertise to be found in the operating agencies. This makes it important that effort be focused on the most important rule-makings, and that it be prompt. No more than a few hundred rules annually, as such, should be in strong review.

cabinet Departments and other governmental agencies? Or is he merely to *oversee* their doing so, accepting that ultimate legal responsibility for action has been placed in them and that his authority is limited to persuasion, to replacing officers whose decisions displease him, and the like?

I have discussed this question at length elsewhere.[65] In a nutshell, my view is that control and influence are different matters. As our one elected executive official with a constitutionally defined active role, the President is certainly entitled to try to influence agencies; he would be shirking if he did not do so. He enjoys constitutional authority to demand the 'Opinion, in writing' from the leadership of executive departments on any matter Congress has assigned to them.[66] Certainly this supposes that, once informed of their opinion, he will have a chance at least to reason with them on any matter Congress has assigned to them (that is, their 'Duties', to which the same constitutional text also refers). For me, this must include the so-called independent regulatory commissions as well as the cabinet departments. And where responsibilities are shared among several agencies—to take an example I am a bit familiar with, radiation exposure protections, which concern the Nuclear Regulatory Commission, EPA, Occupational Safety and Health Administration, the Department of Defense, the Department of Energy, the Department of Transportation (hazmats) and probably others—coordination must be part of what he has to do. He should have staff to help him with this, a matter of particular importance where multiple agencies are involved.

Control, in my judgement, is an entirely different matter. Congress has placed decisional responsibility in the EPA, say, not in the President. That placement, no less than the placing of the Forest Service in the Department of Agriculture and National Parks in the Department of the Interior, is a part of the law to whose faithful execution the President has undertaken to see. He is not assuring the faithful execution of the law if he purports to assign decisional responsibility to a place Congress has not put it, or takes on himself decisional responsibility for a matter Congress has delegated to someone else.

This is not to say that presidential supervision of rule-making is per se inappropriate. It seems at least possible that the new administration will pay more disciplined attention than its predecessors have to the first, priority-setting stage of the executive order process. Priority planning has been a part of the executive order at least since the second Reagan administration, but it has never been seriously used, so far as I have been able to tell. Strikingly, for example, a recent Government Accountability Office (GAO) Report,[67] while paying detailed

Supply cross ref.

[65] PL Strauss, 'Overseer or "The Decider"? The President in Administrative Law' (2007) 75 *Geo Wash L Rev* 695.

[66] US Const art II, § 2, cl 1 (The President 'may require the Opinion, in writing, of the principal Officer in each of the executive Departments, upon any subject relating to *the Duties of their respective Offices*[.]') (emphasis added).

[67] See n [illegible] below.

attention to agency decision processes throughout the initiation and development of rule-makings, essentially ignores the formation of the regulatory plan. Conversations with agencies about their priorities—where the President believes it is important for them to put their effort—is in my judgement far more likely to be effective in improving government performance and administration than retrospectively checking sums on a series of particular rules. So also, engagement with agencies in how they structure their internal processes to promote sound and efficient analysis and decision, downplaying retrospective analysis of what is already well under way. Retrospective analysis threatens, and has been used to secure, considerable delay of initiatives already established as important priorities. And an emphasis on the regulatory plan element may also increase political responsibility *within* agencies. Chris DeMuth, the progenitor of the regulatory plan element, rationalised it as a way to give the political heads within agencies a mechanism for engaging with their staff at the outset of rule-makings, rather than also find themselves caught in retrospective exercises with effective *faits accomplis* perpetuated by staff.

Further, there are certain questions (foreign policy issues for example) as to which there is 'no law to apply', as the courts have said, and federal officials are merely the organs to express presidential will. Chief Justice Marshall famously addressed this setting in *Marbury v Madison*.[68] But where legality is central to our very tolerance of governmental authority, as it is for rule-making decisions like those of the EPA, then in my judgement our President's role under the laws, in a government of laws, requires him to respect Congress's placement of duties where Congress has placed them. When the EPA is authorised to adopt rules, it is the head of the EPA who has the responsibility to decide those matters. The President's place is one of oversight, not decision, making sure that he or she does that well. Which of course includes the agency head's acting only on the basis of those factors Congress has made relevant to his or her decision—precisely the issue President Bush's intervention on ozone appeared to compromise.[69] Of course consultation can often result in pressures, the substitution of judgement in fact. To turn from the presidency for the moment, the courts, too, know that they are responsible to review agency action (oversight) but are not to substitute their own judgements (decision); yet this does not keep them from doing things on occasion that to the observer seem like substitution. The important thing is the attitude—that agencies know what their responsibilities are, that courts are aware that they, like Presidents, are not supposed to substitute judgement, and that onlookers like myself can point to departures and cry 'Shame!'

[68] *Marbury v Madison* 5 US (1 Cranch) 137 (1803): an official obliged 'to conform precisely to the will of the President,' Marshall wrote, 'is the mere organ by whom that will is communicated. The acts of such an officer, as an officer, can never be examinable by the courts. … The province of the court is, solely, to decide on the rights of individuals, not to enquire how the executive, or executive officers, perform duties in which they have a discretion. Questions, in their nature political, or which are, by the constitution and laws, submitted to the executive, can never be made in this court.'

[69] *Massachusetts v EPA* 549 US 497, 533 (2007).

My casebook colleague Todd Rakoff, reading an early draft of this chapter, remarked that it might be useful to note 'that our parties—or those that have a chance of coming to power—are based on very broad coalitions, such that each represents (albeit to differing degrees) most of the views to be found on public policy.' Over the years American political parties have enforced much less rigorous discipline, particularly in the Congress, than the parties of parliamentary democracies often deploy. Absent much party discipline or feeling that it ought to prevail, the result is to make even executive administration quite diverse. As President Harry Truman famously remarked when President Eisenhower, a former general, had been elected to succeed him, 'He'll sit here … and he'll say, "Do this! Do that!" And nothing will happen. Poor Ike—it won't be a bit like the Army. He'll find it very frustrating.'[70] If presidential power is understood as the power to *persuade*—if those with whom he interacts understand that duties lie with them, that loyalty is not the *primum bonum* of holding executive office, and that the diversity of political view within their party creates wiggle room for them in performing their duties—then one might argue that the 2,500 or so presidential administrative appointments made without the benefit of Senate confirmation will still predictably represent, in some crude but real sense, the disparate views of a majority of the population. Introduce the emphasis on loyalty and effective party discipline that has characterised the Republican party in recent years, in Congress as well as in the White House, and this reassurance disappears.[71] The governing ethic of those taking the 'strong unitary executive' view is that the first duties of civilian heads of departments, like generals of the Army, are loyalty and obedience. Recall Truman's quip: 'Whenever you have an efficient government you have a dictatorship.'[72]

Supply cross ref.

Transparency, Accountability, and the Honest Broker

Knowledge of what White House officials are doing is surely a prerequisite for presidential political responsibility, indeed for arming political response. Fortunately, there is at least some reason to believe the present executive order regime can facilitate the necessary watchdogging. The involvement of OIRA is perhaps the most regular and (although not completely) transparent means by which political officials may succeed in influencing decisions ostensibly committed to bureaucrats instructed to act on the basis of objective data and limited, stated considerations.[73] As noted previously, that OIRA's interventions in the ozone

[70] R Neustadt, *Presidential Power and the Modern President* (New York, Free Press, 1991).

[71] *cf* the decision of Senator Arlen Spector, a long-time moderate Republican from Pennsylvania, to switch parties, which appears at least in part to have been motivated by the prospect of strong opposition within his party in a coming election, given his moderate views.

[72] See n [illegible] above.

[73] Accounts of Vice President Dick Cheney's behaviour in office, eg, have included his repeated forceful and undisclosed interventions on a question concerning the amount of water (that might otherwise be used by farmers for irrigation) to be released from a single western dam in order to

rule-making became public owes something to precommitments it had made. These were made as part of the political price exacted by previous Congresses for accepting the role Presidents had established for it; the disclosures also had their source in bureaucratic initiative. And the ensuing proceedings, congressional and judicial, as well as the fact of a searchable Internet database, reflect possible controls on such interventions in the American context. President Obama's apparent taste for other central offices with oversight responsibilities[74] suggests a possible need to generalise these controls.

Supply cross ref.

Indeed, new scholarship highlights a remarkable gap in the public record. In a piece appearing on SSRN,[75] Professor Nina Mendelson persuasively analyses the opaque disconnect between agency reasoning and White House influence.

> reading in and Westlaw searching of Federal Register statements … has yet to reveal an agency stating that executive supervision has resulted in it revising its final decision, choosing one option over another, or electing one interpretation of a statute as opposed to another.[76]

A recently published GAO study of rule development and OIRA reviews suggests that—as proved out in the Ozone case—presidential fingerprints are more readily to be found in rule-making dockets than statements of basis and purpose; the study also suggests considerable deficiencies in the transparency of the present process.[77]

Perhaps our President's promises of transparency will change all this—lift the veil of privilege, expose the influence of values on decision as Professor Mendelson urges. Or perhaps not. The public alarm over President Bush's apparent use of the EO 12,866 procedures to 'bend science' led President Obama, at the very outset of his administration, to announce a sweeping reconsideration of the practice. Without awaiting further public input, he revoked changes that President Bush had made in the order, that obscured the role of the Vice President, required the designation in each agency of political officers directly responsible to him to control rule-making, and expanded the reach and intensity of OIRA's review. This effectively restored it to the shape it had had during the Clinton administration—but in that administration as well the order did not lack critics

protect an endangered species of fish living in the river on which the dam was situated. Under the statute, wisely or not, the farmers' needs were not a relevant consideration; rather, the decision was to be based on a scientific assessment of the survival needs of the endangered species. J Becker and B Gellman, 'Leaving No Tracks', The Washington Post, 27 June 2007, at A1.

[74] See the text above, following . Recent commentary on these offices, strongly suggesting their deficiencies in transparency alongside their legitimacy for securing coordination among the variety of agencies that may be charged with particular elements of a problem, appears in Czar Talk, www.ombwatch.org/node/10403, visited 21 September 2009.

[75] Mendelson, 'Including "Political" Reasons in Agency Decision Making', www.papers.ssrn.com/sol3/papers.cfm?abstract_id=1359287, visited 27 March 2009.

[76] t n 3.

[77] GAO, Report to the Chairman, Committee on Oversight and Government Reform, House of Representatives, 'Federal Rulemaking: Improvements Needed to Monitoring and Evaluation of Rules Development as Well as to the Transparency of OMB Regulatory Reviews', GAO-09–205, April 2009.

of its politicising and delay-promoting possibilities. Perhaps in consequence, President Obama has invited public as well as agency engagement with the question, how the order should be revised. As of 20 April, 183 public comments or meetings had been memorialised on the White House website,[78] reflecting the wide range of views held on the matter.

Strikingly, and perhaps an indicator of the sensitivity about exposing internal executive branch communications that will doubtless complicate President Obama's commitment to transparency, there is not a single comment from a public agency; two meetings are mentioned, but in each case only the names of agency attendees are given.

Indeed, one kind of issue about presidential control with proven implications for 'science-bending' concerns presidential control over executive branch communications with Congress, a sort of control likely to be much harder to achieve where ministers are members of parliament who must be prepared to respond, with their own re-electability on the line, in free flowing 'question time'. Transparency, and all the contributions to 'honest brokering' and effective democracy through the 'marketplace of ideas' that go with it, are impaired if the President takes the position that communications with Congress or the public must be pre-cleared politically. One notorious example during the Bush administration was the suppression of projections concerning the cost of certain health-care measures.

Some White House controls are of long-standing, however. During my tenure as General Counsel of the US Nuclear Regulatory Commission some three decades ago, the Office of Management and Budget was already 'coordinating' (ie, pre-clearing) communications and testimony to Congress about legislative proposals and budgetary matters. The Commission's nominal independence (it was of course an element of the executive branch, but its statutes provided explicitly for direct communication) softened these controls; but, as noted above,[79] within the Commission itself, Bureau 'executives' sometimes kept their staffers on a tight leash in terms of what the latter were permitted to tell the Commission about perceived nuclear energy risks. And similar pressures might be brought to bear on utility personnel to suppress safety concerns they might wish to share with the Commission. Such 'bending' did not conduce to public protection.

Supply cross ref.

The legal basis for sweeping presidential control over communication by others in the executive branch, if not its political reality, can be questioned. To the extent the American Constitution speaks to the matter at all, it merely permits the President to recommend to the Congress such legislation as he regards as expedient. Citizens of parliamentary democracies, inured to the powers of their prime minister over legislative business, will easily grasp the weakness of this

[78] www.reginfo.gov/public/jsp/EO/fedRegReview/publicComments.jsp, visited 10 September 2009.

[79] See n [redacted] ove and accompanying text.

provision, which addresses only presidential initiative and does not even suggest that a presidential suggestion must become legislative business. For that to happen, some member of Congress must introduce a bill, whose language the President cannot legally control. There is nothing here about keeping others from making any recommendations they might like. Nonetheless, as indicated, Presidents have long asserted the right to sit astride any such communications, at least outside the 'independent regulatory commission' context.

The strong Bush (and Reagan) administration theories of the 'unitary executive' can be found in a memorandum entitled 'Authority of Agency Officials to Prohibit Employees from Providing Information to Congress', explaining the withholding of projections of health programme costs from Congress, following a discussion properly reciting the Clinton, etc, invocation of executive privilege in more conventional contexts:

> The foregoing discussion does not mean that an agency's right to supervise its employees' disclosures to Congress is limited to privileged information. The discussion establishes only that the CRS interpretation that the 'right of disclosure' statutes prohibit Executive Branch supervision of employee disclosures unconstitutionally limits the ability of the President and his appointees to supervise and control the dissemination of privileged government information. However, the CRS position also unconstitutionally limits the President's ability to supervise and control the work of subordinate officers and employees of the Executive Branch more generally. See Constitutionality of Statute Requiring Executive Agency to Report Directly to Congress, 6 Op. O.L.C. 632, 633 (1982) (statutory 'requirement that subordinate officials within the Executive Branch submit reports directly to Congress, without any prior review by their superiors, would greatly impair the right of the President to exercise his constitutionally based right to control the Executive Branch'; provision would be unconstitutional if so construed); Authority of the Special Counsel of the Merit Systems Protection Board to Litigate and Submit Legislation to Congress, 8 Op. O.L.C. 30, 31 (1984) ('Congress may not grant [Special Counsel] the authority to submit legislative proposals directly to Congress without prior review and clearance by the President, or other appropriate authority, without raising serious separation of powers concerns').

This second, 'unitary Executive' position is based on the following rationale:

> The [judicial] decisions and the long practical history concerning the right of the President to protect his control over the Executive Branch are based on the fundamental principle that the President's relationship with his subordinates must be free from certain types of interference from the coordinate branches of government in order to permit the President effectively to carry out his constitutionally assigned responsibilities. The executive power resides in the President, and he is obligated to 'take care that the laws are faithfully executed'. In order to fulfill those responsibilities, the President must be able to rely upon the faithful service of subordinate officials. To the extent that Congress or the courts interfere with the President's right to control or receive effective service from his subordinates within the Executive Branch, those other branches limit the ability of the President to perform his constitutional function.

> 6 Op. O.L.C. at 638–39. Based on this rationale, we do not believe that the statutes relied upon by CRS could constitutionally be applied, as CRS would apply them, to the circumstance where a government official instructs a subordinate government employee not to provide an Administration's cost estimates to Congress, whether or not the estimates are viewed as privileged.[80]

On this issue, the Obama administration appears to be sending somewhat mixed signals. The recent executive order on scientific integrity is explicit that:

> (3) … (b) Nothing in this memorandum shall be construed to impair or otherwise affect…:
>
> (ii) functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

This seems to keep OMB's existing controls over direct agency communications firmly in place. On the other hand, the 'whistleblower' provisions of President Obama's directive on scientific integrity reflect one possible step toward openness—hopefully successful in [re]establishing an ethos, if not invariably successful in preventing suppression of data. And in a recent statement accompanying his signing of a piece of complex legislation, explaining his reservations about limited elements of the bill he was permitting to become law,[81] President Obama wrote:

> *Executive Authority to Control Communications with the Congress.* Sections 714(1) and 714(2) in Division D prohibit the use of appropriations to pay the salary of any Federal officer or employee who interferes with or prohibits certain communications between Federal employees and Members of Congress. I do not interpret this provision to detract from my authority to direct the heads of executive departments to supervise, control, and correct employees' communications with the Congress in cases where such communications would be unlawful or would reveal information that is properly privileged or otherwise confidential.[82]

Whether this is simply a reaffirmation that in some cases (nuclear weapons plans, for example) congressional demands for information must be denied in the interest of national security and the like, or rather a continuation of past practices of iron control over what information Congress sees remains to be seen. But note that in this statement President Obama, unlike his predecessors, limits

[80] www.usdoj.gov/olc/crsmemoresponsese.htm, visited 19 March 2009. Shortly before leaving office, President Bush's final Assistant Attorney-General in charge of the Office of Legal Counsel formally withdrew certain OLC opinions embracing 'unitary Executive' reasoning. In doing so, however, he mentioned only some that had become particularly controversial respecting presidential claims to emergency powers in the wake of September 11, 2001 attacks. NA Lewis, 'Memos Reveal Scope of Power Bush Sought in Fighting Terror', NY Times, 3 March 2009, at A1.

[81] On the controversy over 'signing statements', hardly necessary to explore here, see R Cass and PL Strauss, 'The Presidential Signing Statements Controversy' (2007) 16 *William & Mary Bill of Rights Journal* 11.

[82] Press Statement of 11 March 2009, www.whitehouse.gov/the_press_office/Statement-from-the-President-on-the-signing-of-HR-1105/, visited 13 March 2009.

his reservation to 'cases where such communications would be unlawful or would reveal information that is properly privileged or otherwise confidential.' This seems a more limited, and readily accepted, claim than appears in the Bush 'unitary President' explanation.

It is unreasonable to expect presidential-congressional struggles over executive privilege to cease.[83] As Congress itself recognised in including certain exemptions in the Freedom of Information Act, and as President Truman pungently remarked,[84] the President needs candid advice from his subordinates, and candour depends on confidentiality. Where the issue, however, is not advice, but data (viz, projections of the frequency with which orange-bellied parrots would be impinged on wind farm turbine blades at the projected Bald hills facility in Australia), the issues are quite different. The issue will be how widely and aggressively executive privilege is claimed.

Supply cross ref.

One's impression is that the Obama administration understands these issues. But the proof will be in the pudding.

CONCLUSION

In concluding a paper presented to a conference on *global* administrative law, it may be appropriate to remind the reader that these are not simply American issues. One may be certain the issues of science-bending and the possible contributions to its control of transparency are present in *every* administrative law system—if not in connection with rule-making, then with contentious licensing issues.

The Internet and its ready searchability are global phenomena, so that questions about what information it should contain about governmental policy formation, made available to whom, and on what time schedule, are universal. Questions inviting scientific assessment frequently also involve uncertainties not completely resolvable by objective means, and/or kinds of risk to which the public is particularly sensitive. They may reflect matters of large public concern, on which the public, and politicians representing them, will understandably and acceptably wish to have a voice. The use of nuclear power, or of genetically modified organisms (GMOs) in the food chain, and the problems of global warming come readily to mind, and there are many like situations. One easily imagines situations like the more acceptable way of understanding the ozone controversy in the United States, in which generalist politicians are motivated by public interest considerations that may be missing from the particular law governing an agency's resolution of a matter. Understandable as it may be for them to inject these considerations into the decisional framework, that course

[83] See generally PM Shane, 'Negotiating for Knowledge: Administrative Responses to Congressional Demands for Information' (1992) 44 *Administrative Law Review* 197.

[84] See text accompanying [illegible] above.

nonetheless presents troubling questions of legality. If the inadequacy of the existing legal framework is thus revealed, the proper response appears to be changing, not overriding, that framework. Beyond this lies the possibility that, less acceptably, individual politicians will act covertly in the interest of particular 'clients' to influence decision away from the point that an inquiry according to framework laws would determine.

To what extent is the data on which scientific assessments or political judgements may be based provided through the Internet, or in other ways exposed to public view? What are the contexts in which political interventions in an ostensibly objective (scientific) process may arise? To what extent are they transparent, so that the fact of them may be known? What if any controls are available to constrain their impact? These are questions of the broadest import. In the current day, given the high levels of concern about global warming, GMOs, and other matters, finding appropriate space both for the understandings science can bring and for the expression of democratic concerns that do not and need not regard all risks as commensurate, is challenging indeed.

Appendix A

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release March 9, 2009

March 9, 2009

MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

SUBJECT: Scientific Integrity

Science and the scientific process must inform and guide decisions of my Administration on a wide range of issues, including improvement of public health, protection of the environment, increased efficiency in the use of energy and other resources, mitigation of the threat of climate change, and protection of national security.

The public must be able to trust the science and scientific process informing public policy decisions. Political officials should not suppress or alter scientific or technological findings and conclusions. If scientific and technological information is developed and used by the Federal Government, it should ordinarily be made available to the public. To the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking. 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.

By this memorandum, I assign to the Director of the Office of Science and Technology Policy (Director) the responsibility for ensuring the highest level of integrity in all aspects of the executive branch's involvement with scientific and technological processes. The Director shall confer, as appropriate, with the heads of executive departments and agencies, including the Office of Management and

Appendix A

Budget and offices and agencies within the Executive Office of the President (collectively, the 'agencies'), and recommend a plan to achieve that goal throughout the executive branch.

Specifically, I direct the following:

1. Within 120 days from the date of this memorandum, the Director shall develop recommendations for Presidential action designed to guarantee scientific integrity throughout the executive branch, based on the following principles:

(a) The selection and retention of candidates for science and technology positions in the executive branch should be based on the candidate's knowledge, credentials, experience, and integrity;

(b) Each agency should have appropriate rules and procedures to ensure the integrity of the scientific process within the agency;

(c) When scientific or technological information is considered in policy decisions, the information should be subject to well-established scientific processes, including peer review where appropriate, and each agency should appropriately and accurately reflect that information in complying with and applying relevant statutory standards;

(d) Except for information that is properly restricted from disclosure under procedures established in accordance with statute, regulation, Executive Order, or Presidential Memorandum, each agency should make available to the public the scientific or technological findings or conclusions considered or relied on in policy decisions;

(e) Each agency should have in place procedures to identify and address instances in which the scientific process or the integrity of scientific and technological information may be compromised; and

(f) Each agency should adopt such additional procedures, including any appropriate whistleblower protections, as are necessary to ensure the integrity of scientific and technological information and processes on which the agency relies in its decisionmaking or otherwise uses or prepares.

2. Each agency shall make available any and all information deemed by the Director to be necessary to inform the Director in making recommendations to the President as requested by this memorandum. Each agency shall coordinate with the Director in the development of any interim procedures deemed necessary to ensure the integrity of scientific decisionmaking pending the Director's recommendations called for by this memorandum.

3. (a) Executive departments and agencies shall carry out the provisions of this memorandum to the extent permitted by law and consistent with their statutory and regulatory authorities and their enforcement mechanisms.

(b) Nothing in this memorandum shall be construed to impair or otherwise affect:

(i) authority granted by law to an executive department, agency, or the head thereof; or

(ii) functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

c) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at 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.

4. The Director is hereby authorized and directed to publish this memorandum in the Federal Register.

BARACK OBAMA

Appendix B

WORKING PRINCIPLES FOR RISK ANALYSIS FOR FOOD SAFETY FOR APPLICATION BY GOVERNMENTS

CAC/GL 62–2007

1. SCOPE

1. The Working Principles for Risk Analysis for Food Safety for Application by Governments are intended to provide guidance to national governments for risk assessment, risk management and risk communication with regard to food related risks to human health.

2. GENERAL ASPECTS

2. The overall objective of risk analysis applied to food safety is to ensure human health protection.

3. These principles apply equally to issues of national food control and food trade situations and should be applied consistently and in a non discriminatory manner.

4. To the extent possible, the application of risk analysis should be established as an integral part of a national food safety system.[85]

5. Implementation of risk management decisions at the national level should be supported by an adequately functioning food control system/program.

6. Risk analysis should be:

- applied consistently;
- open, transparent and documented; and

Are footnotes added by author so correct to continue numbering as here, or are they in the original document so should be 1,2 etc?

[85] It is recognised that national governments will use different approaches and time frames in the application of these principles taking into account national capacities and resources.

- evaluated and reviewed as appropriate in the light of newly generated scientific data.

7. The risk analysis should follow a structured approach comprising the three distinct but closely linked components of risk analysis (risk assessment, risk management and risk communication) as defined by the Codex Alimentarius Commission,[86] each component being integral to the overall risk analysis.

8. The three components of risk analysis should be documented fully and systematically in a transparent manner. While respecting legitimate concerns to preserve confidentiality, documentation should be accessible to all interested parties.[87]

9. Effective communication and consultation with all interested parties should be ensured throughout the risk analysis.

10. The three components of risk analysis should be applied within an overarching framework for management of food related risks to human health.

11. There should be a functional separation of risk assessment and risk management to the degree practicable, in order to ensure the scientific integrity of the risk assessment, to avoid confusion over the functions to be performed by risk assessors and risk managers and to reduce any conflict of interest. However, it is recognized that risk analysis is an iterative process, and interaction between risk managers and risk assessors is essential for practical application.

12. Precaution is an inherent element of risk analysis. Many sources of uncertainty exist in the process of risk assessment and risk management of food related hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis. The assumptions used for the risk assessment and the risk management options selected should reflect the degree of uncertainty and the characteristics of the hazard.

13. National governments should take into account relevant guidance and information obtained from risk analysis activities pertaining to human health protection conducted by Codex, FAO, WHO and other relevant international intergovernmental organizations, including OIE and IPPC.

[86] See Definitions of Risk Analysis Terms Related to Food Safety, Procedural Manual.

[87] For the purpose of the present document, the term 'interested parties' refers to 'risk assessors, risk managers, consumers, industry, the academic community and, as appropriate, other relevant parties and their representative organizations' (see definition of 'Risk Communication').

14. With the support of international organizations where appropriate, national governments should design and/or apply appropriate training, information and capacity building programs that are aimed to achieve the effective application of risk analysis principles and techniques in their food control systems.

15. National governments should share information and experiences on risk analysis with relevant international organisations, other national governments (e.g. at the regional level through FAO/WHO Regional Coordinating Committees) to promote and facilitate a broader and, where appropriate, more consistent, application of risk analysis.

3. RISK ASSESSMENT POLICY

16. Determination of risk assessment policy should be included as a specific component of risk management.

17. Risk assessment policy should be established by risk managers in advance of risk assessment, in consultation with risk assessors and all other interested parties. This procedure aims at ensuring that the risk assessment is systematic, complete, unbiased and transparent.

18. The mandate given by risk managers to risk assessors should be as clear as possible.

19. Where necessary, risk managers should ask risk assessors to evaluate the potential changes in risk resulting from different risk management options.

4. RISK ASSESSMENT

20. Each risk assessment should be fit for its intended purpose.

21. The scope and purpose of the risk assessment being carried out should be clearly stated and in accordance with risk assessment policy. The output form and possible alternative outputs of the risk assessment should be defined.

22. Experts, involved in risk assessment including government officials and experts from outside government should be objective in their scientific work and not be subject to any conflict of interest that may compromise the integrity of the assessment. Information on the identities of these experts, their individual expertise and their professional experience should be publicly available, subject to national considerations. These experts should be selected in a transparent manner on the basis of their expertise and their independence with regard to the interests involved, including disclosure of conflicts of interest in connection with risk assessment.

23. Risk assessment should incorporate the four steps of risk assessment, i.e., hazard identification, hazard characterization, exposure assessment and risk characterization.

24. Risk assessment should be based on scientific data most relevant to the national context. It should use available quantitative information to the greatest extent possible. Risk assessment may also take into account qualitative information.

25. Risk assessment should take into account relevant production, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection and the prevalence of specific adverse health effects.

26. Constraints, uncertainties and assumptions having an impact on the risk assessment should be explicitly considered at each step in the risk assessment and documented in a transparent manner. Expression of uncertainty or variability in risk estimates may be qualitative or quantitative, but should be quantified to the extent that is scientifically achievable.

27. Risk assessments should be based on realistic exposure scenarios, with consideration of different situations being defined by risk assessment policy. They should include consideration of susceptible and high-risk population groups. Acute, chronic (including long-term), cumulative and/or combined adverse health effects should be taken into account in carrying out risk assessment, where relevant.

28. The report of the risk assessment should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment. Minority opinions should also be recorded. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessors.

29. The conclusion of the risk assessment including a risk estimate, if available, should be presented in a readily understandable and useful form to risk managers and made available to other risk assessors and interested parties so that they can review the assessment.

5. RISK MANAGEMENT

30. National government decisions on risk management, including sanitary measures taken, should have as their primary objective the protection of the health of consumers. Unjustified differences in the measures selected to address similar risks in different situations should be avoided.

31 Risk management should follow a structured approach including preliminary risk management activities,[88] evaluation of risk management options, implementation, monitoring and review of the decision taken.

32. The decisions should be based on risk assessment, and should be proportionate to the assessed risk, taking into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade, in accordance with the Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles[89] as they relate to decisions at the national level. National Governments should base their sanitary measures on Codex standards and related texts, where available.

33. In achieving agreed outcomes, risk management should take into account relevant production, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection, feasibility of enforcement and compliance, and the prevalence of specific adverse health effects.

34. Risk management should take into account the economic consequences and the feasibility of risk management options.

35. The risk management process should be transparent, consistent and fully documented. Decisions on risk management should be documented so as to facilitate a wider understanding of the risk management process by all interested parties.

36. The outcome of the preliminary risk management activities and the risk assessment should be combined with the evaluation of available risk management options in order to reach a decision on management of the risk.

37. Risk management options should be assessed in terms of the scope and purpose of risk analysis and the level of consumer health protection they achieve. The option of not taking any action should also be considered.

38. Risk management should ensure transparency and consistency in the decision-making process in all cases. Examination of the full range of risk management options should, as far as possible, take into account an assessment

[88] For the purpose of these Principles, preliminary risk management activities are taken to include: identification of a food safety problem; establishment of a risk profile; ranking of the hazard for risk assessment and risk management priority; establishment of risk assessment policy for the conduct of the risk assessment; commissioning of the risk assessment; and consideration of the result of the risk assessment.

[89] See *Statements of Principle Concerning the Role of Science in the Codex Decision Making Process and the Extent to which other Factors are Taken in to Account*, Procedural Manual.

of their potential advantages and disadvantages. When making a choice among different risk management options, which are equally effective in protecting the health of the consumer, national governments should seek and take into consideration the potential impact of such measures on trade and select measures that are no more trade-restrictive than necessary.

39. Risk management should be a continuing process that takes into account all newly generated data in the evaluation and review of risk management decisions. The relevance, effectiveness, and impacts of risk management decisions and their implementation should be regularly monitored and the decisions and/or their implementation reviewed as necessary.

6. RISK COMMUNICATION

40. Risk communication should:

i) promote awareness and understanding of the specific issues under consideration during the risk analysis;

ii) promote consistency and transparency in formulating risk management options/recommendations;

iii) provide a sound basis for understanding the risk management decisions proposed;

iv) improve the overall effectiveness and efficiency of the risk analysis;

v) strengthen the working relationships among participants;

vi) foster public understanding of the process, so as to enhance trust and confidence in the safety of the food supply;

vii) promote the appropriate involvement of all interested parties;

viii) exchange information in relation to the concerns of interested parties about the risks associated with food; and

ix) respect the legitimate concern to preserve confidentiality where applicable.

41. Risk analysis should include clear, interactive and documented communication, amongst risk assessors and risk managers and reciprocal communication with all interested parties in all aspects of the process.

42. Risk communication should be more than the dissemination of information. Its major function should be to ensure that all information and opinion required for effective risk management is incorporated into the decision making process.

43. Risk communication involving interested parties should include a transparent explanation of the risk assessment policy and of the assessment of risk, including the uncertainty. The decisions taken and the procedures followed to reach them, including how the uncertainty was dealt with, should also be clearly explained. It should indicate any constraints, uncertainties, assumptions and their impact on the risk analysis, and minority opinions that had been expressed in the course of the risk assessment (see para. 28).

Appendix C

DECLARATION OF INTERESTS FOR FAO EXPERTS

The assistance of distinguished authorities knowledgeable in a variety of scientific professions is essential to the work of the Food and Agriculture Organization of the United Nations (FAO). **It is expected that persons qualified to serve as an expert for FAO may have private interests related to the subject of their expertise. At the same time, it is imperative that situations be avoided in which such interests may unduly affect, or may be perceived to affect, an expert's impartiality or the outcome of work in which he/she was involved.**

To assure the highest integrity, and hence public confidence, in the activities of the Organization, FAO's regulations and policies require that all experts serving in an advisory role disclose any circumstances which could give rise to a potential conflict of interest (i.e., any interest which may affect, or may reasonably be perceived to affect, the expert's objectivity and independence). Accordingly, in this Declaration of Interest (DOI) form, you are requested to disclose any financial, professional or other interest relevant to the subject of the work or meeting in which you will be involved and any interest that could be significantly affected by the outcome of the meeting or work. You are also asked to declare relevant interests of others who may, or may be perceived to, unduly influence your judgment, such as immediate family members, employers, close professional associates or any others with whom you have a substantial common personal, financial or professional interest. If you do not provide, where requested, the amount or value of the interest, it will be assumed to be significant.

Kindly complete this form and submit it to FAO Secretariat, well in advance of the meeting or work. You are also asked to inform the Secretariat of any change in this information that occurs before or during the course of the meeting or work. If FAO considers that a potential conflict of interest exists, one of several outcomes can occur, depending on the circumstances involved: (i) you may be invited to continue to participate in the meeting or work, provided that your interest would be publicly disclosed; (ii) you may be asked not to take part in the portion of the meeting, discussion or work related to your interest, or not participate in related decisions; or (iii) you may be asked not to take part in the meeting or work altogether. Non-completion of the DOI form would preclude further consideration of an expert's participation.

Appendix C

Experts are requested to agree that any relevant conflicts may be **publicly disclosed** to other meeting participants and in the resulting report or other work product. The Secretariat will assume that you consent to such a disclosure, unless you check 'no' in the space provided on the last page of this form. In addition, the information disclosed by you **may later be made available** to persons outside of FAO if the objectivity of the work or meeting in which you are involved is questioned and the Director-General considers disclosure to be in the best interests of the Organization, although only after discussion with you.

Date and title of meeting or work, including description of subject-matter to be considered (if a number of substances or processes are to be evaluated, a list should be attached):

_____

_____

Please answer each of the questions below. If the answer to any of the questions is 'yes', briefly describe the circumstances on the last page of the form.

The term 'you' refers to yourself, your employer and your immediate family members (i.e., spouse (or partner with whom you have a similar close personal relationship) and your minor children). The term 'commercial entity' includes—aside from any commercial venture—an industry association, research institution or other organization whose funding is significantly derived from commercial concerns having an interest related to the subject of the meeting or work. The term 'meeting' also includes a series or cycle of meetings.

EMPLOYMENT AND CONSULTING

Within the past 3 years, have you worked for a commercial entity or other organization with an interest related to the subject of the meeting or work? Please also report any application or negotiation for future work.

1a	Employment	Yes □ No □
1b	Consulting, including service as a technical or other advisor	Yes □ No □

RESEARCH SUPPORT

Within the past 3 years, have you or your department or research unit received support or funding from a commercial entity or other organization with an interest related to the subject of the meeting or work? Please also report any application or award for future research support.

2a	Research support, including grants, collaborations, sponsorships, and other funding	Yes□ No □

2b	Non-monetary support valued at more than US$1000 overall (include equipment, facilities, research assistants, paid travel to meetings, etc.)	Yes □ No □
	INVESTMENT INTERESTS Do you have current investments (valued at more than US$10 000 overall) in a commercial entity with an interest related to the subject of the meeting or work? Please also include indirect investments such as a trust or holding company. You may exclude mutual funds, pension funds or similar investments that are broadly diversified.	
3a	Stocks, bonds, stock options, other securities (e.g., short sales)	Yes□ No □
3b	Commercial business interests (e.g., proprietorships, partnerships, joint ventures)	Yes □ No □
	INTELLECTUAL PROPERTY Do you have any current intellectual property rights that might be enhanced or diminished by the outcome of the meeting or work?	
4a	Patents, trademarks, or copyrights (also include pending applications)	Yes □ No □
4b	Know-how in a substance, technology or process	Yes □ No □
	PUBLIC STATEMENTS AND POSITIONS (during the past 3 years) (questions relate to balanced composition of committee or group)	
5a	As part of a regulatory, legislative, judicial, or other governmental process, have you provided an expert opinion or testimony, related to the subject of the meeting or work, for a commercial entity or other organization?	Yes □ No □
5b	Through your articles, editorials or speeches, could you be perceived as having taken a prominent or well-known position related to the subject of the meeting or work?	Yes □ No □
5c	Do you hold an office or other position, paid or unpaid, where you may be expected to represent interests or defend a position related to the subject of the meeting or work?	Yes □ No □
5d	Have you served as a principal investigator, as lead expert in an expert committee or scientific or advisory group, and/or a member of a steering committee, an advisory board or equivalent body in relation to the same product or subject matter?	Yes □ No □

Appendix C

ADDITIONAL INFORMATION

6a If not already disclosed above, have you worked for the competitor of a product which is the subject of the meeting or work, or will your participation in the meeting or work enable you to obtain access to a competitor's confidential proprietary information, or create for you a financial or commercial competitive advantage? Yes□ No □

6b To your knowledge, would the outcome of the meeting or work benefit or adversely affect interests of others with whom you have substantial common personal, financial or professional interests (such as your adult children or siblings, close professional colleagues, administrative unit or department)? Yes□ No □

6c Is there any other aspect of your background or present circumstances not addressed above that might be perceived as affecting your objectivity or independence? Yes □ No □

EXPLANATION OF 'YES' RESPONSES: If the answer to any of the above questions is 'yes', check above and briefly describe the circumstances on this page. If you do not provide, where requested, the amount or value of the interest, it will be assumed to be significant.

Nos. 1–4 Type of interest, question number and category (e.g., Intellectual Property 4.a copyrights) and basic descriptive details.	**Name of company, organization, or institution**	**Belongs to you, a family member, employer, research unit or other?**	**Amount of income or value of interest (if not disclosed, assumed significant)**	**Current interest (or year ceased)**
Nos. 5–6: Describe the specific circumstances, parties involved, time frame and other relevant details				

CONSENT TO DISCLOSURE. The Secretariat will assume that you consent to the disclosure of any relevant conflicts to the other meeting participants and in the resulting report or work product, unless you check 'no' in the space provided here. If you check 'no', the Secretariat will not disclose the information without your prior approval, although this may result in your not being able to participate in the meeting or conference. **No:** □

Appendix C

DECLARATION. I hereby declare that the disclosed information is true and complete to the best of my knowledge. I undertake to inform the responsible staff of FAO of any change in this information or any new information that needs to be reported, which occurs before or during the meeting or work itself and through the period up to the publication of the final results.

Date: _____Signature_____

Name

Institution

Address

Fax

Email

Telephone

UNITED STATES

NUCLEAR REGULATORY COMMISSION

WASHINGTON, D. C. 20555

No. 76-12
Contact: Joseph J. Fouchard
Tel. 301/492-7771

FOR IMMEDIATE RELEASE
(Mailed - January 20, 1976)

NRC INVESTIGATES EMPLOYEE'S ALLEGATIONS

The Nuclear Regulatory Commission has directed two senior officials--the Director of the Office of Nuclear Reactor Regulation and the Agency Inspector--to investigate an employee's allegations concerning reactor safety and his claim that individual staff views have been disregarded by the NRC management system.

Chairman William A. Anders said today he first learned of the allegations of Robert Pollard, an electrical engineer in the Office of Nuclear Reactor Regulation--and of Pollard's resignation from NRC--from Mike Wallace of CBS during the filming of an interview on January 13. Pollard had handed the resignation to his supervisor a few minutes earlier.

During the interview with Anders, Wallace described what he said were Pollard's general concerns about NRC management, and some more specific safety points he said Pollard has raised concerning the Indian Point Station in New York. Pollard has been coordinating the NRC staff licensing review of Indian Point III.

Both Chairman Anders and Benard C. Rusche, Director of the Office of Nuclear Reactor Regulation, have talked at length with Pollard since he submitted his resignation January 13. Though NRC is still working to obtain more specificity with regard to Pollard's concerns, all of the safety issues that he has raised so far with the Commission already had been thoroughly examined by other members of NRC's technical staff and had previously been resolved during the licensing review. But, Pollard apparently is dissatisfied with the way those issues were resolved.

The Commission is proceeding with its investigation to review the staff's consideration and disposition of the safety issues which Pollard identifies.

Additionally, the NRC Inspector has been directed to look into the process by which employee views and concerns are made known internally and evaluated.

"As a key ingredient to executing our responsibilities for public health and safety, the Commission is interested in assuring that there is adequate opportunity for staff members to communicate their views to top management levels," Anders said. "For that reason we have directed our Agency Inspector, Thomas McTiernan, to look into this aspect of Mr. Pollard's allegations."

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Appendix D

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July 1, 2011

Angela Nugent, Ph.D.
Designated Federal Officer, EPA Science Advisory Board
Special Assistant to the Director, EPA SAB Staff Office
U.S. Environmental Protection Agency (1400R)
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Public Involvement in EPA Advisory Activities
Supported by the SAB Staff Office

Dear Ms. Nugent:

I am writing in response to the request for comments contained in the SAB's May 11, 2011 Federal Register notice (76 Fed. Reg. 27315). I appreciate your email of May 31, in which you indicated that you would like comments to be submitted by June 30. I trust you will still consider these.

I. Background & Qualifications

I am filing these comments on my own behalf, as someone who has worked for a more than a quarter century on issues involving EPA's use of science. I spent 14 years at the American Chemistry Council, where these issues were always in play, and for almost four years have represented a number of clients on the same types of matters. I've published several articles on agency use of science, and I am the creator and managing editor of the ENVIRONMENTAL SCIENCE DESKBOOK.[1] I specialize in administrative law, the field of law applicable to the topic of the SAB's notice, and am currently the Vice-Chair of the American Bar Association's Section of Administrative Law & Regulatory Practice.[2] Of particular relevance, in 2008 I participated in an OMB Watch-sponsored committee studying public participation in agency activities.[3]

[1] http://west.thomson.com/environmental-science-deskbook-law-series/5051/16624886/productdetail.
[2] These comments are my own and do not necessarily reflect the views of the ABA or the Section.
[3] http://www.hks.harvard.edu/hepg/Papers/transparencyReport.pdf.

II. Executive Summary

These comments make specific recommendations regarding two of the specific topics identified in the Staff Office's notice. They are limited to the SAB, as that is the entity supported by the Staff Office with which I have the most experience.

Public Involvement in Nomination of Experts for Committees and Panels. The Staff Office generally interprets applicable laws, rules and policies appropriately as they apply to the SAB, although it is too conservative as it interprets the concept of lack of impartiality. The Office should forthrightly recognize that all experts have biases and that the solution is not to disqualify them but to balance them with experts having countervailing biases.

Public Involvement in Meetings and Report Development. The SAB's current approach to public involvement could be summarized as "All Talk, No Interaction." SAB should revamp its public involvement processes to promote more engagement among panelists, Agency staff and external stakeholders, using as its model the kinds of symposia and forums that academics and scientific societies use to ventilate and deliberate on issues – not legalistic frameworks. In particular:

The Charge. The Staff Office could promote the independence of the SAB and increase the quality and acceptance of its work by accepting the charge submitted by EPA as a draft, inviting public comment on it, and negotiating the terms of the charge with the relevant EPA office.

Information-Gathering Sessions. The Staff Office should follow the example of the National Academies and have each SAB panel conduct, at the outset of its work, a public, face-to-face meeting dedicated to gathering information and views regarding the state of the science relevant to the charge. *This is the most important recommendation contained in this letter.*

Subsequent meetings. These should also be made more interactive, to promote substantive dialogue among panel members and interested experts.

More effective use of written comments. The Staff Office should make the document under review available to the public at the same time that it is being made available to reviewers, give the public adequate time to review it and to formulate comments, and provide those comments to panelists in time for them to read them before their meeting.

III. Public Involvement in Nomination of Experts for Committees and Panels.

As the SAB Staff Office is aware, the process of choosing individuals to serve on the SAB is governed by the Federal Advisory Committee Act (FACA), Federal ethics laws and rules (particularly the rules of the Office of Government Ethics), and the OMB *Peer Review Bulletin*. The Staff Office generally interprets these authorities appropriately as they apply to the SAB, although it is too conservative as it interprets the concept of lack of impartiality.

A. In General

The Staff Office appropriately treats members of the SAB as "Special Government Employees," thus subjecting them to the Federal ethics laws and rules. The Staff Office has wisely not adopted the view of some agencies (e.g., DOI, DOE and USDA) that experts serving on advisory bodies are "representatives" of interests and thus exempt from ethics requirements.[4] The Staff Office correctly interprets FACA's "fairly balanced" requirement to refer to the range of respectable scientific and technical perspectives on an issue and not to political perspectives.[5]

B. Over-Conservatism Regarding Appearance of Lack of Impartiality

I am concerned, however, that the Staff Office has been overly conservative in its interpretation of the OGE rules regarding the appearance of lack of impartiality.[6] In a meeting on June 22 sponsored by the Small Business Administration's Office of Advocacy, former SAB Deputy Director Tony Maciorowski stated that the Staff Office had not issued a waiver of this requirement in the past ten years, at least. In effect, any public statement by a person that tends to indicate a view on a relevant issue, or any potentially biasing employment, has resulted in such persons being rendered ineligible for service on a panel. I would recommend that the Staff Office review the

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[4] GAO, the Administrative Conference of the United States and public interest groups have all opposed this practice. *See* Government Accountability Office, GAO-04-328, *Federal Advisory Committees – Additional Guidance Could Help Agencies Better Ensure Independence and Balance* 13 (April 2004); ACUS Recommendation 89-3, *Conflict-of-Interest Requirements for Federal Advisory Committees*, 54 Fed. Reg. 28969 (July 10, 1989); Center for Progressive Reform, *Saving Science from Politics: Nine Essential Reforms of the Legal System* 25 (2008).

[5] SAB, *Overview of the Panel Formation Process at the Environmental Protection Agency Science Advisory Board* 10 (Sept. 2002), available at http://yosemite.epa.gov/sab/sabproduct.nsf/WebFiles/OverviewPanelForm/$File/ec02010.pdf; *accord* OMB, *Final Information Quality Bulletin for Peer Review*, 70 Fed. Reg. 2664, 2669 (Jan. 14, 2005).

[6] 5 C.F.R. § 2635.502.

statements of the National Academies, and even EPA's own *Peer Review Handbook*, on this topic. For example, the National Academies Policy states that:

> Questions of lack of objectivity and bias ordinarily relate to views or positions taken that are largely intellectually motivated or that arise from the close identification or association of an individual with a particular point of view or the positions of a particular group.[7]

It adds that such biases should not be disqualifying – even where a person works for a company with "a general business interest in" the subject of the panel -- unless the person "is totally committed to a particular point of view and unwilling, or reasonably perceived to be unwilling, to consider other perspectives or relevant evidence to the contrary." The National Academies Policy is widely supported, from industry groups to NGOs.[8]

The Peer Review Handbook similarly recognizes that "experts with a stake in the outcome – and therefore a conflict or appearance issue – may be some of the most knowledgeable and up-to-date experts because they have concrete reasons to maintain their expertise."[9] Consistently with the National Academies Policy, it states that, "[a]s a general rule, experts . . . *who have clearly 'taken sides,'* may have an appearance of a lack of partiality . . . and should be avoided."[10]

These statements regarding the correlation of "interest" issues and expertise have been empirically confirmed by the FDA. An FDA contractor studied the issue and found that advisory committee members who were given conflict of interest waivers had greater levels of expertise than those that were not.[11] Presumably a similar correlation would hold between appearances of lack of impartiality and expertise.

Outside of cases of conflict or extreme bias, the National Academies' solution is not to disqualify people with biases, but to appoint other people with offsetting biases:

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[7] National Academies, *Policy on Committee Composition & Balance and Conflicts of Interest for Committees Used in the Development of Reports* 3 (May 12, 2003), available at http://www.nationalacademies.org/coi/bi-coi_form-0.pdf.

[8] For example, the Center for Progressive Reform states: "As the [National Academies'] guidelines recognize, some degree of bias is unavoidable. . . . On the other hand, when biases become so strong that they impinge on an individual's ability to objectively answer new questions, that person should not be given the institutional power of an advisory committee member." *Saving Science from Politics, supra* note 4.

[9] EPA Science Policy Council, PEER REVIEW HANDBOOK 70 (3d ed. May 2006), *available at* http://www.epa.gov/peerreview/pdfs/Peer%20Review%20HandbookMay06.pdf.

[10] *Id*. at 63 (emphasis added).

[11] ERG, *Measuring Conflict of Interest and Expertise on FDA Advisory Committees* (2007), available at http://www.fda.gov/oc/advisory/ergcoireport.pdf

"Indeed, it is often necessary, in order to ensure that a committee is fully competent, to appoint members in such a way as to represent a balance of potentially biasing backgrounds or professional or organizational perspectives."[12] This solution is also advocated by the seminal report of the Bipartisan Policy Center (BPC)'s Science for Policy Project: "[T]he goal should be to ensure that the overall committee is balanced."[13]

I submit that the Staff Office would benefit by applying the standards of the National Academies, the BPC and the *Peer Review Handbook*, looking for the individuals with the greatest expertise on the relevant topics, accepting public statements or employment in connection with the issue unless they indicate an unwillingness to consider issues fairly,[14] and issuing waivers of the requirement for lack of impartiality in appropriate circumstances.[15]

C. SAB's Public Involvement Process

The SAB's process of involving the public in its choice of experts may well be a best practice across the Federal government. The wide cast/narrow cast process appropriately:

- Solicits nominations of potential panelists from the public (even the National Research Council does not do this); and
- Solicits public comments on the draft slate of panelists.

The SAB should continue this process. I would make one recommendation here, designed to help establish a panel's independence from EPA: the Staff Office should require EPA to nominate any potential reviewers that it would like to suggest, and it should note the identity of the nominating person or entity when it posts the lists of proposed and final panelists.

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[12] National Academies Policy, *supra* note 7, at 3.
[13] BPC, IMPROVING THE USE OF SCIENCE IN REGULATORY POLICY 24 (August 2009), available at http://www.bipartisanpolicy.org/sites/default/files/BPC%20Science%20Report%20fnl.pdf.
[14] For example, a statement that no further research on a topic would be warranted, or service as an expert witness in litigation, might indicate that a person is "totally committed to a particular point of view and unwilling, or reasonably perceived to be unwilling, to consider other perspectives or relevant evidence to the contrary."
[15] I would also urge the Staff Office to apply the standards of the *Peer Review Bulletin* in assessing the potential for Agency funding to render a prospective panelist not independent. *See* 70 Fed. Reg. 2669.

IV. Public Involvement in Meetings and Report Development.

A. My Organizing Principle: Look More to Science than Law

I commend the Staff Office for convening the June 1 meeting and inviting input on the topic of involving the public in meetings of the SAB and otherwise in their development of reports. I have a series of recommendations, explained below. Part of the motivation for these recommendations is the due process intuition that, in a free and democratic nation, persons who are affected by the work of a government agency (including its advisory bodies) are entitled to have an appropriate amount of input into those decisions.

But the Staff Office should not regard this issue solely as one of satisfying legalities. Of at least equal importance is the likelihood that external parties have greater scientific and technical expertise than Agency staff and potentially even members of SAB panels. The Staff Office's procedures should be designed to take maximum advantage of that expertise.

Indeed, my recommendations are that those procedures should be *less* legalistic than they are now, and should more closely resemble the norms of scientific discourse in which panel members accustomed to engaging in their normal professional lives, outside of their service on SAB. "Opportunities for comment" and "responses to comments" are really creatures of administrative law, designed to reassure judges. I challenge the Staff Office to develop public involvement processes that are modeled on the dialogic processes used by scientific bodies and societies to try and assess the weight of the relevant evidence and the merits of competing explanatory hypotheses. SAB should not become "science courts," but they could do a better job of serving as scientific bodies.

B. The Charge

Logically and temporally, the first step in improving public involvement in the work of the SAB is to improve the way the charge for these bodies is developed. The Staff Office has heard repeated complaints from panel members, as well as the public, about charges that seem to be drafted intentionally to divert panels' attention from issues that EPA would prefer to avoid. A prominent recent example is the SAB's work on the IRIS assessment for inorganic arsenic, in which SAB members complained about "the elephant in the room here" – the narrowness of the charge questions:[16]

[16] SAB, Quality Review Teleconference (Nov. 22, 2010), transcript at 155.

> [G]iven that there is a fair amount of discomfort both from the public comments and from several members of the SAB around that . . . narrow focus[, the SAB should offer to] do an integrated review . . ., in fact, do what I think everyone really had hoped we would do from the get-go.[17]

At present, EPA largely presents the charge to the Staff Office as a fait accompli. I recommend that the Staff Office essentially follow the model of the NRC:

- Accept the charge submitted by EPA as a draft.
- Publish a notice of the draft charge, inviting public comment on it. This will enable the staff office to gain the benefit of others' views on relevant issues and how the charge might ideally be phrased.
- Negotiate the terms of the charge with the relevant EPA office, both before and after those comments are received.[18]
- Permit the panel to seek to renegotiate the charge with EPA (through the Staff Office) where panel members feel that is truly warranted.

The foregoing steps should maximize the likelihood that the charge:

- Addresses the full range of relevant issues;
- Does not presuppose any conclusions; and
- Avoids tasking SAB with answering policy questions.

They will also help ensure that the SAB is truly independent of EPA, as it prides itself in being.[19]

Based on this charge, the Staff Office can then choose a panel that contains the range of expert perspectives that the charge question(s) require. (This process is discussed in Part III above.)

C. The Information Gathering Session

Of all the recommendations in this submission, the one requiring the most dramatic departure from current Staff Office practice is this one: that all SAB panels should conduct, at the outset of their work on any particular charge, a public, face-to-face meeting dedicated to gathering information and views regarding the state of the science relevant to the charge. This is not a novel concept for advisory bodies – NRC panels typically conduct an information-gathering session as part of their first meeting. And EPA begins the process of each five-year NAAQS revision by holding a

[17] *Id*. at 117.
[18] Among other things, the SAB might choose to avoid answering essentially editorial charge questions about how well a document is drafted, etc.
[19] *See Overview of the Panel Formation Process, supra* note 5, at 2.

public workshop to determine the state of the policy-relevant science as of that point. But SAB panels have not customarily begun their deliberations with this sort of forum, and I submit this omission has rendered some panels' work unnecessarily complicated and has lessened the quality of their final reports from what it could have been.

In essence, the purpose of an information gathering session is "crowd-sourcing"; to ensure that the panel is aware of the full range of relevant information, as identified by interested stakeholders, and the perspectives of those stakeholders as to:

- which studies are most significant and why;
- which studies may be confounded or have other shortcomings;
- which modes of action are most plausible; and
- the major sources of uncertainty.

In order for these sessions to be most productive, they should begin with a presentation by EPA staff regarding the work (or question) to be reviewed and the reasons motivating the charge question. Panel members would be encouraged to question staff.

Following the EPA presentation, but while Agency staff remained, interested stakeholders would be given time to make presentations regarding the relevant science. Again, panel members would be encouraged to question the presenters. A facilitator (which could be the panel chair, the DFO for the panel, or a contractor), would administer this portion of the process. These presentations could be time-limited, but those limits should be scaled to the importance of the issue and the amount of information that each presenter seeks to convey. They could well vary depending on the presenter. They should not be arbitrarily limited to three or five minutes, however.

Ideally, the panel would allow the various presenters, EPA and stakeholder representatives, to ask each other questions and engage in debate. For example, presenters might be seated at tables where they could remain and engage in discussion after they had concluded their individual presentations. Certainly the Staff Office should experiment with this approach. If it determined that the process was too difficult to manage effectively, the process could be conducted like Congressional hearings; i.e., stakeholders and Agency staff would not permitted to question each other, but panel members could ask each questions raised by the other.

In appropriate cases, it might be worthwhile for the facilitator to present a relevant analytical framework (e.g., the IPCS Framework for Analyzing the Relevance of a Cancer Mode of Action for Humans) and invite presenters to explain how they

would apply it to the existing body of science. Presenters might also be invited to prepare standardized evidence tables illustrating their analysis of the literature. Such a focused set of presentations and discussions could be particularly useful when the SAB is being asked to review an IRIS assessment.

In designing and piloting this process, the Staff Office should be motivated principally by the desire to facilitate and maximize authentic engagement among professionals – as opposed to the current "all talk, no interaction" approach. The Staff Office should use as its model the kinds of symposia and forums that academics and scientific societies use to ventilate and deliberate on issues.

Inherent in this proposal is that presenters would have scientific or technical expertise, as indicated by job title, academic credentials, authorship of papers or articles, etc. On topics of great public controversy, it might be necessary to have a separate public comment period for individuals not claiming (or credibly able to substantiate) such expert status. Implementing this distinction will require some degree of judgment, but it should not be a sufficient reason not to pursue the idea.

It is often difficult for the regulated community to ascertain the basis for the Agency's selection of studies, or choice of methodology for assessing risk, and as a result some conclude that EPA is attempting to covertly bias the reports that it issues. Greater participation by Agency scientists in forums of this sort would demonstrate a willingness to delineate the bases for those choices and engage in discussion on their merits, and could go a long way toward dispelling such perceptions of bias.

D. Subsequent Sessions

The SAB currently receives public comments at designated periods during its face-to-face meetings. It should continue to involve the public at public meetings after the proposed information gathering/state of the science session. While these public input opportunities need not be structured like that event, the Staff Office should undertake to make all of them more interactive, to promote substantive dialogue among panel members and interested experts.

E. Written Comments

For "highly influential scientific assessments," OMB's *Peer Review Bulletin* requires that,

> [w]henever feasible and appropriate, the agency shall make the draft scientific assessment available to the public for comment at the same time it is submitted for peer review (or during the peer review process) and

> sponsor a public meeting where oral presentations on scientific issues can be made to the peer reviewers by interested members of the public. When employing a public comment process as part of the peer review, the agency shall, whenever practical, provide peer reviewers with access to public comments that address significant scientific or technical issues. To ensure that public participation does not unduly delay agency activities, the agency shall clearly specify time limits for public participation throughout the peer review process.[20]

Following this direction, and as a best practice in cases that might not meet the definition of "highly influential scientific assessments," the SAB should:

- Notify the public of the availability of the report (or other materials) being supplied to the panel, at the same time that it is being made available to reviewers;

- Give the public adequate time to review the report and to formulate comments (generally 30 days, and potentially longer for major documents; and

- Provide the public comments to the reviewers in time for them to be able to read them before the panel's meeting (at least a week). The Staff Office should design its website such that comments filed electronically would be automatically posted on the site and an email notice sent to panel members notifying them that comments had been posted and of the identity of the commenter. The Staff Office should not collect comments and then submit them to reviewers in batches.

Notably, I am not recommending that SAB prepare "response to comments" documents addressing the comments submitted by the public. Such exercises are an example of the legalistic model that I am urging the Staff Office to avoid emulating. If the panels' reports are thorough and the comments are raise important issues, the report will by necessity end up addressing those topics. If it does not, that omission will be obvious and will not reflect well on the report or the panel members.

F. Feasibility

In making the foregoing proposals, I am sensitive to concerns that they will require additional meeting time and staff effort, and would be risky (as all innovations are). However, I also note Mr. Maciorowski's statement at the June 22 SBA session that 70% of SAB meetings have no public comments. I should think it would be a rare

[20] 70 Fed. Reg. 2676.

review where the initial information gathering session could not be conducted in a single day or less.

While these recommendations might encourage a greater degree of participation, it seems likely that, in most cases, no one will sign up for the public involvement aspect of meetings, and things will proceed as they do now. And to the extent that these proposals to engender greater public participation, I posit that this will be a good thing from the perspective of improving the overall quality of the SAB' work.

* * *

Once again, I commend the Staff Office for seeking the public's views on how to increase public involvement in the SAB' formation and report development. As can be seen, I think doing so will only increase the quality of those reports, as well as the credibility of the SAB. I encourage the Staff Office to be bold in its innovations, and thank you for the opportunity to provide you with these recommendations.

Sincerely,

James W. Conrad, Jr.

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December 15, 2011

Via Electronic Submission

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Committee on Regulation
http://www.acus.gov/forum/

Re: Comments on Science in the Administrative Process, 76 Fed. Reg. 64,298 (Oct. 18, 2011)

Dear Professor Wagner:

On behalf of the Styrene Information and Research Center, Inc. (SIRC),[1] we are pleased to provide comments on your research concerning "Science in the Administrative Process," conducted under the auspices of the Administrative Conference of the United States (ACUS). As stated in the draft outline, the study focuses on "strengthening internal agency processes for communicating how it uses science for regulation."[2]

I. What is Science?

The current administration has consistently highlighted the relationship between science and governance. President Obama called for the restoration of science in his inaugural address,[3] the Office of Science and Technology Policy disseminated administrative guidelines for ensuring

[1] The Styrene Information and Research Center, Inc. (SIRC) was formed in 1987 as the principal focal point for public information and research on styrene. It is a non-profit organization consisting of voting member companies involved in the manufacturing or processing of styrene, and associate member companies that fabricate styrene-based products. Collectively, SIRC's membership represents approximately 95% of the North American styrene industry. SIRC serves as a liaison between industry, federal and state governments, and international agencies on health-related issues involving styrene. For more information visit: www.styrene.org.

[2] "Science in the Administrative Process: Take 2 (Draft Outline)," Wendy Wagner, University of Texas School of Law (Oct. 30, 2011), *available at* http://www.acus.gov/wp-content/uploads/downloads/2011/10/COR-Science-Project-Wagner-outline-10-31-11.pdf.

[3] *See* January 20, 2009 Inaugural Address, *available at* http://www.whitehouse.gov/blog/inaugural-address/.

"scientific integrity,"[4] and Administrator Jackson of the United States Environmental Protection Agency (EPA) commenced her tenure by directing employees not to disguise policy decisions as scientific findings.[5] Strengthening internal communication processes is a critical first step in enabling agencies to effectively use science.

There is a substantial body of literature on science and governance. Much of that literature focuses on the inevitable challenges to democratic principles presented by a seemingly endless stream of government decisions based on complex science, of which the majority of citizens either lack the ability or interest to gain an understanding.[6] Those issues are largely outside the scope of this inquiry, but underscore the need for agencies to communicate science in a straight-forward manner so that the average person can understand the basis for concern and, thus, should not be ignored in developing a framework for internal agency communications.

Before addressing science in the administrative process, the current study would be well-served by discussing or defining what is meant by science within the context of the paper. Even the term scientific method has a number of meanings. In general, we may say that the scientific method involves careful, systematic and open reasoning about empirical evidence.

Another meaning of scientific method refers to the process of observation, development of a hypothesis and predictions based on that hypothesis, followed by experimentation, the results of which are used to validate or refine the hypothesis and, ultimately, to develop a theory that consistently and accurately predicts the phenomena being observed. In this sense, a theory is a logical and consistent model or framework that describes some aspect of our observable universe. While the scientific method is widely taught, there is a body of literature that criticizes this formulation as an inadequate or misleading description of the basis for scientific progress or discovery.[7] We agree that this strict definition does not sufficiently embrace scientific *thinking*.

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[4] *See* "Memorandum for the Heads of the Executive Departments and Agencies on Scientific Integrity," from John P. Holdren, Director of the Office of Science and Technology (Dec. 17, 2010), *available at* http://www.whitehouse.gov/sites/default/files/microsites/ostp/scientific-integrity-memo-12172010.pdf.

[5] *See* "Opening Memorandum to EPA Employees," from EPA Administrator Lisa P. Jackson (Jan. 23, 2009), *available at* http://blog.epa.gov/administrator/2009/01/26/opening-memo-to-epa-employees/.

[6] *See, e.g.*, Sheila Jasanoff, "Technologies Of Humility: Citizen Participation In Governing Science," Minerva 41:223-244 (2003). Sheila Jasanoff is Pforzheimer Professor of Science and Technology Studies at Harvard University's John F. Kennedy School of Government. Her publications include *The Fifth Branch: Science Advisers as Policymakers* (Harvard University Press, 1990). A Science and Democracy Network bibliography is available at: http://www.hks.harvard.edu/sdn/bibliography/.

[7] Some examples include: Thomas S. Kuhn, "The Structure of Scientific Revolutions," N.R. Hanson, "Patterns of Discovery," and Paul Feyerabend, "Against Method." Suspicion followed by discovery is "the core of the empirical program of quantitative natural science." Fred L. Bookstein, "Geometry as Cognition in the Natural Sciences." The easiest, quick read on this are postings by Dr. Terry Halwes, who appears to be a professor in the Department of

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Steven Schafersman makes a helpful distinction between the scientific method and scientific reasoning.

> *The scientific method is practiced within a context of scientific thinking, and scientific (and critical) thinking is based on three things: using empirical evidence (empiricism), practicing logical reasoning (rationalism), and possessing a skeptical attitude (skepticism) about presumed knowledge that leads to self-questioning, holding tentative conclusions, and being undogmatic (willingness to change one's beliefs). These three ideas or principles are universal throughout science; without them, there would be no scientific or critical thinking.*[8]

Valid implementation of the scientific method has practical implications for a wide array of agencies.[9]

II. Common and Unshared Aspects of Science and the Administrative Process

While the predominant view treats science and the administrative process as two very different types of endeavors, a premise of these comments is that there are many similarities meriting emphasis. After all, the essence of both disciplines is process: the process of discovery governed by the scientific method in science; and the process of rulemaking governed by the Administrative Procedure Act in federal agencies. Using the examples below, we compare scientific and administrative processes. This is one starting point for clarifying the intent of administrative practices among agency scientists. It may also refine the agency's managers on the role and limits of science in the administrative process.[10] Discussions of such comparisons can themselves lead to improved understanding and communication.

For example, well-designed test protocols are a cornerstone of experimental science. To produce comparable and reliable data, however, good laboratory practices are needed to implement test protocols properly. By analogy, administrative procedures are akin to test protocols. Without the right procedures, the probability of obtaining valid and meaningful results is very low. But, even with the right procedures, administrative proceedings need the equivalent of good

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Psychiatry at Yale University School of Medicine, available at: http://www.dharma-haven.org/science/myth-of-scientific-method.htm.

[8] Steven D. Schafersman, "An Introduction to Science: Scientific Thinking and the Scientific Method" (Jan. 1994), *available at* http://www.freeinquiry.com/intro-to-sci.html.

[9] *See, e.g.,* "Report on the Relationship of the Scientific Method to Scientifically Valid Research and Education Research," prepared for the U.S. Department of Education Institute of Education Sciences by Norman W. Edmund, Edmund Scientific Co. (Dec. 2005).

[10] *See Reference Manual on Scientific Evidence*, Federal Judicial Center and National Research Council, pp. 51-52 (3d ed. 2011) (discussing how science and the law imprint on the same language different meanings, but despite these differences both disciplines share many of the same methods).

laboratory practices in terms of implementation. An agency may provide a comment period, but if the comments are not considered in a meaningful way, the intent of the procedural step is not realized. For scientists, applying the empiricism, rationalism and skepticism found in scientific thinking to the task at hand would be essential to establish a solid foundation for any administrative endeavor.

A. A Common Aspect: Replication and Transparency

In experimental science, the study report or manuscript must contain enough detail that other researchers can replicate the test protocol and compare their results with the original research. That replication or lack of replication will validate, modify, or invalidate the insights learned from the initial study.[11]

This ability to replicate is very much like the concept of transparency that is stressed in administrative proceedings. Transparency is used prominently in President Obama's guidance, in Lisa Jackson's 2009 memo on transparency in EPA operations, in the Information Quality Act, and in the National Research Council's review of EPA's Draft IRIS Assessment of Formaldehyde.[12]

Particularly in a democracy, the public needs to be able to walk, step-by-step, through the agency's decision-making process; we need to be able to follow the agency's line of reasoning and recreate the objective data on which it was based. This process, in many respects, is as important as the decision itself.

Besides serving the fundamental values of participatory democracy, this approach also serves the agency's institutional needs. Such a record is helpful for EPA when staff members review or revisit prior assessments. It also serves as a reference point or point of departure when the agency, guided by new data or direction, decides to change its approach.

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[11] The inability to replicate the results of scientific experiments has a broad array of consequences and its own implications for the use of science in the administrative process. The implications for commercial enterprises was the subject of a front page story in December 2, 2011, edition of the Wall Street Journal. The article was entitled "Scientists' Elusive Goal: Reproducing Study Results" (roughly 20% of academic studies being fully replicated, 64% not being replicated and the balance being partially replicated), available at http://online.wsj.com/article/SB10001424052970203764804577059841672541590.html?KEYWORDS=reproducing+study+results (subscription required).

[12] *See especially*, chapter 7, "Roadmap for Revision." The entire report is available as a free download at: http://www.nap.edu/catalog.php?record_id=13142.

B. Uncommon Aspects

While fact-based, logical and open-minded analysis are common process aspects of both science and the administrative process, agency communications would also benefit by understanding and respecting the differences between science and the administrative process. Indeed, many of the criticisms related to science and the administrative process have stemmed from the errors of ignoring scientific information or using science as a stealth mask for statutory or policy-based risk management decisions.

Agency reviews and analyses of the available scientific information would benefit by carefully honoring the scientific method within a framework and culture that nurtures scientific discourse. The role of the staff scientist can be unduly influenced in two ways. First, there can be agency demands for scientific conclusions when the level of uncertainty does not permit conclusions. Second, the operating culture within an agency can be influenced through the bias of viewpoints or considerations not appropriate to an open and objective review of the current state of the science. Embracing and elucidating the distinction between science and regulatory policy is critical to ensuring scientific integrity and enhancing policy debates in risk management decision-making.

For example, care should be taken to distinguish between data, the interpretation of data, the application of policy and the application of statutory or regulatory criteria to risk management decisions. Science is amoral. It is a wonderful vehicle for determining the degree of certainty related to a particular event, be it the time of the sun rise or the probability of developing cancer from certain behaviors. But, science does not inherently carry ethical, social or moral values for the events or processes it helps us to understand.[13] It is society's choice whether it builds power plants or makes bombs, or what levels of resources are applied to those endeavors. Science may inform our choices, and risk assessment is a valuable tool to sharpen our logic and understanding of potential outcomes, but the governmental risk management decision is necessarily made and applied within a statutory or legal framework.

[13] We stress that the amoral nature of the scientific process relates to the absence of a scientific ethic directing how new learning or abilities should be used. In contrast, the scientific process itself relies on the truthfulness of scientists in presenting protocols and results as well as transparency. External transparency may be intentionally avoided, for example, in matters of national security, and, in the private sector, to protect potential commercialization. National security or other considerations may be valid reasons for avoiding external transparency, but internal agency transparency should be observed to the greatest extent possible to facilitate internal agency communications. Personal privacy rights are an additional consideration, for example, with regard to the subjects of health studies.

The Bipartisan Policy Center explains it thus:

> *[D]ecisions about how much risk society should tolerate or what actions should be taken in the face of scientific uncertainty are not science questions, rather they concern policies and values. Matters such as risk and uncertainty need to be informed by scientific results, but science cannot tell policy makers how to act. True, distinguishing between science and policy is not always easy or straightforward, and scientists may make choices based on values in the course of their work. Nonetheless, policy debate would be clarified and enhanced if a systematic effort were made to distinguish between questions that can be resolved through scientific judgments and those that involve judgments about values and other matters of policy when regulatory issues comprise both*.[14]

III. Communicating Clearly

This section presents suggestions to guide internal agency communications. While it focuses on internal practices, the application of good internal communication practices should improve the agency's ability to communicate to the public, in an intelligible manner, the bases for its decision.

A. "Science" versus "Regulatory Science"

The term "regulatory science" refers to agency scientific reviews conducted for the purpose of applying statutory or regulatory criteria to determine whether regulatory action is necessary and, if so, whether the proposed action is the appropriate one.[15] It is well recognized that regulatory science, produced to support governmental efforts to guard against risk, is fundamentally different from research driven by scientists' collective curiosity.[16] The development and use of regulatory science typically involves three distinct processes:

1. the development and collection of scientific data;
2. the interpretation and evaluation of scientific data; and

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[14] Bipartisan Policy Center, "Improving the Use of Science in Regulatory Policy" p. 15 (Aug. 5, 2009), *available at* http://www.bipartisanpolicy.org/sites/default/files/BPC%20Science%20Report%20fnl.pdf.

[15] *See, e.g.*, 42 U.S.C. § 241(b)(4), requiring that the Secretary of the Department of Health and Human Services publish a biennial report which contains a list of all substances (1) which either are known to be carcinogens or may reasonably be anticipated to be carcinogens; and (2) to which a significant number of persons residing in the United States are exposed.

[16] Sheila Jasanoff, "Technologies of Humility: Citizen Participation in Governing Science." Minerva 41: 223-244, 229 (2003).

3. the application of criteria or "regulatory policy" to the scientific findings for purposes of making a risk management decision.

While an agency may, and indeed should, apply the scientific method in the first two stages, regulatory science departs from the traditional scientific discipline at stage three, where statutory or regulatory criteria and other value-based inputs come to bear.

For substances with either limited or extensive scientific literature, evaluating their potential toxicological effects presents challenges in the context of data interpretation and evaluation. Limited databases frequently call for extrapolation, while extensive databases regularly require the reconciliation of divergent results. In this regard, it is important to recognize and explain the relationships between data, interpretation of data, and the application of scientific principles and regulatory policy. The agency must determine, as a matter of policy, how to reconcile scientific uncertainty, weigh risk, and decide what approach is appropriate, taking into account the nature of the public health risk, the benefits that the chemical provides to society and the applicable legal criteria.

Agencies can strengthen accountability by developing internal guidelines and protocols that help clarify for both officials and the general public which aspects of a risk management decision are truly about scientific data and which concern policy. Indeed, the credibility of regulatory science ultimately rests upon factors that have more to do with transparency and accountability, than with the quality of science as assessed by review panels.[17] Such protocols should address how the agency plans to approach the three distinct stages involved in regulatory science reviews (*i.e.*, data collection, data interpretation and evaluation, and application of regulatory policy to scientific findings) in a logical and transparent manner, and should include the following accepted principles for communicating science in the administrative process:

- Agency communications relating to a proposed action should describe the primary scientific questions and the primary policy questions that need to be answered.[18] This should be combined with an explanation of the scientific procedure employed, and what policies were applied in the staff report. Importantly, individual determinations or recommendations that support the ultimate decision need to be separately stated and explained to provide a complete understanding of the policy or risk management decision the recommendations embody.
- If the available scientific literature leaves a significant level of uncertainty as to the degree to which effects can be predicted, this should be explicitly recognized and not hidden by seemingly precise impressions of numeric projections. For example, the available data might limit an agency's ability to prepare a quantitative risk assessment.

[17] *See id.* at 233.

[18] *Supra* note 14.

Such uncertainty may prompt the agency scientists to apply multiple safety factors under various science policies, resulting in a policy determination that a very low numeric value will be designated as a safe level. The scientific staff needs to scrupulously describe how it interpreted the scientific data and the default assumptions it employed. But agency scientists need to be equally clear in explaining the limits of knowledge and uncertainty, what science policies were applied, and the risk management implications. The agency risk manager needs to understand the range of projections so that final rules avoid the unintended extremes.

- Agencies must avoid disguising policy decisions as scientific findings,[19] and framing regulatory issues as debates solely about science.[20] Instead, in any draft or final document concerning science, agencies should clarify that they are not presenting scientific fact, but rather a policy judgment informed by their scientific literature review and their interpretation of the applicable statutory or regulatory criteria.[21]

B. Agencies and Their Review Panels Must Define the Scope of the Literature Review and Describe the Uncertainties and Limitations of Such Data

In any regulatory science review, the agency scientists should describe the criteria they use to determine which scientific papers to review and how those papers will be evaluated, and the proposed criteria should be open for public comment as early in the process as possible.[22] The clarification of these criteria will serve to gain early stakeholder consensus and reduce the likelihood of potential challenges to the quality, reliability and agency interpretation of scientific data late in the scientific review process. The benefits of "early" peer review are recognized by the Office of Management and Budget's (OMB) *Final Information Quality Bulletin for Peer Review*:

> *[I]n the context of risk assessments, it is valuable to have the choice of input data and the specification of the model reviewed by peers before the agency invests time and resources in implementing the model and interpreting the results. "Early" peer review occurs in time to focus attention on data inadequacies in time for corrections*.[23]

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[19] *Supra* note 5.

[20] *Supra* note 14 at 11.

[21] *See* "Final Information Quality Bulletin for Peer Review," Memorandum from Joshua B. Bolten, Director, Office of Management and Budget to Heads of Departments and Agencies, p. 15 (Dec. 16, 2004) (citing Mark R. Powell, *Science at EPA: Information in the Regulatory Process*, Resources for the Future, Washington, D.C., 1999: 139).

[22] *Supra* note 14 at 41.

[23] *Supra* note 21 at 14.

To this end, agencies should establish transparent protocols and standards for data identification, interpretation and characterization in conformity with the National Academy of Sciences recommendations. Such an approach includes:

- Establishing standard protocols for evidence identification;
- Developing a template for description of the search approach;
- Establishing protocols for review of major types of studies, such as epidemiologic and bioassay;
- Standardizing the approach to using weight-of-evidence guidelines;
- Conducting agency workshops on approaches to implementing weight-of-evidence guidelines;
- Expanding and harmonizing the approach for characterizing uncertainty and variability; and
- Establishing clear guidelines for study selection, which include balancing the strengths and weaknesses of studies, weighing human versus experimental evidence, and determining whether combining estimates among studies is warranted.[24]

When circulating draft and final hazard assessments for review, the agency staff should clearly describe the relevant positive and negative evidence, the limitations inherent in the data, and the uncertainties and divergent results presented. As emphasized in the White House's Memorandum on Scientific Integrity:

> *The accurate presentation of scientific and technological information is critical to informed decision-making by the public and policymakers. Agencies should communicate scientific and technological findings by including a clear explication of underlying assumptions; accurate contextualization of uncertainties; and a description of the probabilities associated with both optimistic and pessimistic case projections, including best-case and worst-case scenarios where appropriate.*[25]

Such transparency will not only ensure informed decision-making, but will also reduce the likelihood of legal challenges to the regulatory action and increase the probability that, in the event of a legal challenge, the regulatory action stemming from a scientific review is upheld by reviewing bodies, such as a court.

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[24] *See*, National Academy of Sciences "Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde," Ch. 7 (Apr. 2011), *available at* http://www.nap.edu/catalog/13142.html.

[25] *Supra* note 4 at 2.

C. Meaningful and Timely Scientific Dialogue Among the Agency, its Review Panels, and the Outside Scientific Community

The first step to strengthening how agencies communicate science is *communication*. Put simply, agencies must strengthen the dialogue between the staff, agency review panels, and the outside scientific community in order to draw upon the available expertise and diversity of scientific perspectives.[26] OMB's *Final Information Quality Bulletin for Peer Review* recognizes the value of obtaining diverse scientific input:

> *On most controversial issues, there exists a range of respected scientific viewpoints regarding interpretation of the available literature. Inviting reviewers with competing views on the science may lead to a sharper, more focused peer review. Indeed, as a final layer of review, some organizations (e.g., the National Academy of Sciences) specifically recruit reviewers with strong opinions to test the scientific strength and balance of their reports.*[27]

We recognize that the focus of the ACUS study paper is internal agency communications. In many or most cases, however, the agency does not complete its internal communications before engaging in external communications. Particularly when review panels and the outside scientific community are engaged by the agency, the same principles of transparent communication and process should be observed. The need to engage all members of the scientific community, within and outside the agency, is especially critical in light of steadily diminishing government funding for research and increased expectations that industry bear the burden of proving the safety of their chemicals, products and practices.

The agency should also seek to gain outside scientific input because the most relevant, current data are typically developed and best-understood by outside stakeholders with the resources and interest to support such work. In conjunction with an appropriately broad charge, agencies must provide to the members of their review panels all relevant studies brought to light through public comment so that the reviewers can render a meaningful weight of evidence evaluation.[28] Mere access to such information in a public docket is simply not enough given the volume of information submitted and the time constraints of peer review. A good faith agency effort to ensure sound peer review would include providing reviewers with accurate and helpful summaries of critical public comments. Engagement with outside scientists should go beyond brief comment periods, and should include established practices of the scientific community, such as the holding of symposia.

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[26] *See supra* note 21 at 16-17 (stating that the two critical factors in selecting reviewers is expertise and balance).

[27] *Id*.

[28] *See* "OMB Proposes Draft Peer Review Standards for Regulatory Science," p. 4, Office of Management and Budget (Aug. 29, 2003).

Finally, it is critical that agencies provide *timely* responses to relevant comments from the public and their own review panels. Although this may serve external communications purposes at some point, the initial value is a support for careful internal review and critique of agency work product. Carefully reviewing and preparing written responses to comments before starting the next step in a policy-setting process helps to ensure that the agency has the benefit of data and analyses from a variety of sources early in the process, before the agency staff has committed to an unsubstantiated or malformed position. Further, the analysis of and responses to relevant outside comments, especially those that differ from the agency's position, are necessary for effective final work product.

D. Some Final Points

- Public trust in agency expertise and decision-making stems, in large part, from a perception of fair and reasoned decision-making. This is particularly true in the context of regulatory science, as the vast majority of the public lacks the solid grounding in basic sciences, scientific principles and the scientific method necessary to critically assess science in the administrative process. Accordingly, to strengthen the communication of science, agencies should develop a transparent framework setting forth how they will consistently approach and distinguish between scientific data, the interpretation and evaluation of data, and regulatory policy. While these concepts are necessarily inseparable in the context of regulatory science, their roles are unique and limited. Scientific data in isolation rarely answer the questions posed by Congress, the White House or regulatory agencies. To formulate an answer the data must be interpreted, and after the data are interpreted the agency must decide, *as a matter of policy*, how to reconcile scientific uncertainty, weigh risk, and determine appropriate administrative action. Protocols for approaching the stages involved in risk management decision-making would undoubtedly strengthen agency accountability and reliance on agency expertise.
- Agency documents should clarify that they are not presenting scientific fact, but rather a policy judgment informed by their scientific literature review and the applicable statutory or regulatory criteria.
- As a corollary, agencies must explicate - on the science side - the scope of their literature review, the limitations, uncertainties and divergent results of the data, their assumptions and their methods of analysis, and - on the policy side - the statutory or regulatory criteria, as well as the impact of the regulatory decision.
- Prior to beginning the review of scientific data, agencies should explain and seek substantive guidance on their approach to conducting a literature review and their methods for filtering and evaluating studies. Once the agency has committed to a position, early review of methodology will ultimately save resources by minimizing the likelihood of legal challenges that would otherwise arise near the end of an assessment.

- Review panels must be given enough time and a broad enough charge to review relevant stakeholder input and additional scientific data, to identify scientific uncertainties and to characterize the potential implications of those uncertainties on the technical conclusions drawn.
- If a risk profile does not clearly satisfy the legal criteria for regulatory action, then briefing memoranda and other correspondence directed to agency heads should scrupulously describe how the staff interpreted the scientific data and the default assumptions they employed.

IV. Conclusion

Good science and good administrative practices share common elements and should be mutually reinforcing. Internal agency communications would benefit by ensuring transparency and meaningful, timely dialogue among the agency, its review panels, and outside stakeholders. While these principles would benefit many types of administrative processes, they are essential in the field of "regulatory science," where the amoral discipline of science and the value-based exercise of policymaking come together. In this context, transparency includes clearly distinguishing the roles science, data interpretation, and regulatory policy play in administrative risk management decision-making.

We appreciate the opportunity to provide our comments on this important issue and would be happy to discuss or elaborate as the project progresses.

Respectfully submitted,

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